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HEALTH STATUS AND HEALTH-RELATED QUALITY OF LIFE

IN CONGESTIVE HEART FAILURE

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE

DEGREE OF DOCTOR OF PHILOSOPHY

IN THE GRADUATE SCHOOL OF THE

TEXAS WOMAN'S UNIVERSITY

COLLEGE OF NURSING

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BY

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DENTON, TEXAS

DECEMBER 2008

TEXAS WOMAN'S UNIVERSITY
DENTON, TEXAS

October 23, 2008

To the Dean of the Graduate School:

I am submitting herewith a dissertation written by Karen Elaine Ainsworth Landry entitled "Health Status and Health-Related Quality of Life in Congestive Heart Failure." I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a major in Nursing Science.

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DEDICATION

To my father, Bobby Lynn Ainsworth,
who passed away in 2004 of an acute cardiac
event while I was pursuing this degree.
Thank you for your love, support and guidance.

ACKNOWLEDGMENTS

I would first like to thank God for giving me the opportunity to pursue such an honorable degree and the strength to endure such an endeavor. This journey has had many high points; however, it has certainly brought many challenges as well. During it all, the Lord has never left me nor forsaken me and I give Him all the glory.

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Finally, I would like to thank my many friends and colleagues who have given me support and counsel while pursuing this degree, especially friends who have listened to me after very long days, faculty who have taught in my place, and the many nurses who encouraged me along the way.

ABSTRACT

KAREN ELAINE AINSWORTH LANDRY

HEALTH STATUS AND HEALTH-RELATED QUALITY OF LIFE IN CONGESTIVE HEART FAILURE

DECEMBER 2008

Congestive heart failure (CHF) is a major public health concern today with a high mortality rate. The major purpose of this study was to examine the health status and health-related quality of life (HRQOL) of men and women with a diagnosis of CHF. A cross-sectional exploratory design was used. Specific study aims were to determine (a) whether there were differences in self-reported health status and HRQOL of men and women with CHF, (b) whether the variables of age, race/ethnicity, living status, number of comorbidities, perceived general health status, and perceived symptom management differ by gender, and (c) whether gender, age, race, number of comorbidities, living status, perceived general health status, perceived symptom management perceived physical health status, and perceived mental health status predict HRQOL. A non-probability convenience sample of 113 participants, who met the criteria for participation, were recruited from two cardiac clinics. There were no significant differences among gender categories on the variables of health status and HRQOL. Independent samples *t*-test showed no significant differences in age, total number of comorbidities, perceived general health status, and perceived symptoms management by gender. Chi-square test results revealed that gender and living status were independent, as were gender and race/ethnicity. Hierarchical

regression analysis showed all predictors for each hypothesized dependent variable in the model contributed to the outcome. Perceived symptoms management was a direct predictor of functional status, and its prediction of the mental health component of functional status represented the model's highest relationship. The model's only nonsignificant path was from comorbidities to HRQOL. The variables of perceived general health status, physical health status, mental health status, and perceived symptom management contributed to the HRQOL outcome when age, but not comorbidities, was the exogenous variable. Using kappa, agreement regarding functional status was only 44% between patients and their healthcare providers, adjusted to 37% for chance agreement. The understanding gained from this study will provide guidance in planning future education and interventions for CHF patients.

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CHAPTER I

INTRODUCTION

Congestive heart failure (CHF) is a chronic illness resulting in frequent hospitalizations and death. Those living with CHF experience progressive effects that lead to reduced health status and quality of life (QOL). Overall poor QOL is a predictor of mortality and hospital readmissions (Mejhert, Kahan, Person, & Edner, 2006). Hospital discharges for CHF increased from 399,000 in 1979 to 1,093,000 in 2003, representing an increase of 174%. In 2003, there were 2.4 million males and 2.6 million females with CHF, and the related mortality during that year was 22,300 for males and 34,900 for females (American Heart Association [AHA], 2006).

Research related to gender differences, health status, and health-related quality of life (HRQOL) in persons with CHF has been limited. Riedinger, Dracup, Brecht, Padilla, Sarna, and Ganz (2001) found that women had a poorer QOL than men. Specifically, women had lower physical and social functioning. In seeming opposition to these findings, a study by Evangelista, Kagawa-Singer, and Dracup (2001) showed that health perceptions in women were higher than those of men. Women had better psychosocial adjustment to their illness than did men who verbalized a greater negative feeling concerning their illness. In a more recent study, Jessup and Pina (2004) proposed a theory of gender-related survival rates in myocardial injury. This theory demonstrates injury to the myocardial muscle as it relates to gender differences in cardiac decomposition or

CHF, suggesting why survival rates are different between women and men. This theory that hypothesizes that women have a later onset of cardiac decomposition than men could support the explanation of the larger number of female deaths as compared to males.

Within the nursing literature, limited information on gender specific evidence-based nursing interventions for CHF patients has been found. The proposed study will improve the understanding of gender differences in health status and health-related quality-of-life (HRQOL). This knowledge will help provide future guidance in gender-specific education and interventions for CHF patients.

Problem of Study

The purpose of this proposed study is to examine the health status and HRQOL of men and women with a diagnosis of CHF. The following specific aims initially identified were to determine (a) whether there are differences in self-reported health status and HRQOL of men and women with CHF; (b) whether the variables of age, race/ethnicity, living status, number of comorbidities, perceived general health status, and perceived symptom management differ by gender; and (c) whether gender, age, race, number of comorbidities, living status, perceived general health status, perceived symptom management, perceived physical health status, and perceived mental health status predict HRQOL. The knowledge gained by this study will help healthcare providers understand and create evidence-based nursing interventions to improve health status and HRQOL with attention to gender differences.

Rationale for the Study

CHF is a serious chronic disease with high mortality. It affects 5 million Americans, and approximately 550,000 new cases will be diagnosed each year (AHA, 2006). According to the AHA (2004), 5 years after being diagnosed with CHF, the mortality rate is more than 50%. Under the age of 65, about 80% of men and 70% of women who have heart failure will die within 8 years (AHA, 2004). Clearly then, CHF has a profound impact on individuals in a relatively short span of time. The problem is that there is very little information on gender differences and health outcomes as it relates to HRQOL and health status in CHF patients. Understanding the variables that impact the quality of life can help clinicians target interventions to support and maximize quality of life among individuals with CHF.

CHF is a major economic concern. The amount of dollars spent on the care and treatment of individuals diagnosed with CHF is on the rise. Patients who have Medicare represent the largest insurance group with hospitalizations related to heart failure, with African-Americans having a higher number of hospital admissions than Caucasians (CDC, 2005). The cost of CHF is staggering with an estimated direct cost of 26.8 billion dollars (AHA, 2006). As a result of soaring health care costs and a rise in readmissions, research on the effects of HRQOL on people diagnosed with CHF is greatly needed.

The proposed study will focus on possible gender differences related to health status and HRQOL of persons diagnosed with CHF and on variables that influence HRQOL. Wilson and Cleary (1995) developed a conceptual model of patient outcomes as

it relates to HRQOL. The model is based on a continuum beginning with biological and physiological variables at one end and moving progressively to symptom status, functional status, general health perceptions and overall quality of life. For example, coronary artery disease can lead to CHF. Symptoms of CHF are dyspnea or shortness of breath, fatigue, swelling of the extremities, and coughing. These symptoms can alter the individual's functional capacity and difficulties with activities of daily living. Socialization and psychological functions can be affected by the decrease in physical function. All of the concepts identified by Wilson and Cleary contribute to the patient's health perception and the patient's HRQOL is formed from the relationships in this process. In summary, HRQOL is grounded in the patient's biological and physiological properties, symptom and functional status, and health perceptions.

Key concepts in this proposed study based on Wilson and Cleary's (1995) model are biological and physiological variables (age, gender, race, comorbidities), symptom status (perceived management of symptoms), functional status (perceived physical status and perceived mental status), general health perceptions, and overall quality of life (HRQOL).

HRQOL will be used in this study as it specifically addresses the quality of life of patients with CHF. Mejhert, Kahan, Person, and Edner (2006) found that poorer QOL was associated with mortality and re-hospitalizations. Age and functional class were predictive of mortality in patients with CHF (Cowie et al., 2002). Research studies have shown that there are gender differences (Chin & Goldman, 1998; Friedman, 2003; Gott et al., 2006; Hussey & Hardin, 2003; Jessup & Pina, 2004; Riedinger, Dracup, Brecht,

Padilla, Sarna, & Ganz, 2001; Riedinger, Dracup, Brecht, Padilla, Sarna, & Ganz, 2002).

By determining the variables that predict HRQOL and whether there are gender differences in health status and HRQOL in individual's diagnosed with heart failure, knowledge will be generated that can assist nurses in planning relevant interventions that could improve the lives of CHF patients.

Conceptual Framework

Wilson and Cleary's (1995) health-related quality of life conceptual model will guide this study (Figure 1). The model incorporates a multifaceted approach using five main concepts which are staged so that they occur in order: biological and physiological variables, symptom status, functional status, general health perceptions, and overall quality of life. In the proposed model, the exogenous variables (i.e., gender, age, race/ethnicity, and comorbidities) and the end-stage variable of HRQOL are mediated by symptom status (i.e., perceived symptom management) functional status (i.e., living status, perceived physical health status and perceived mental health status) and general health perceptions (i.e., perceived general health status).

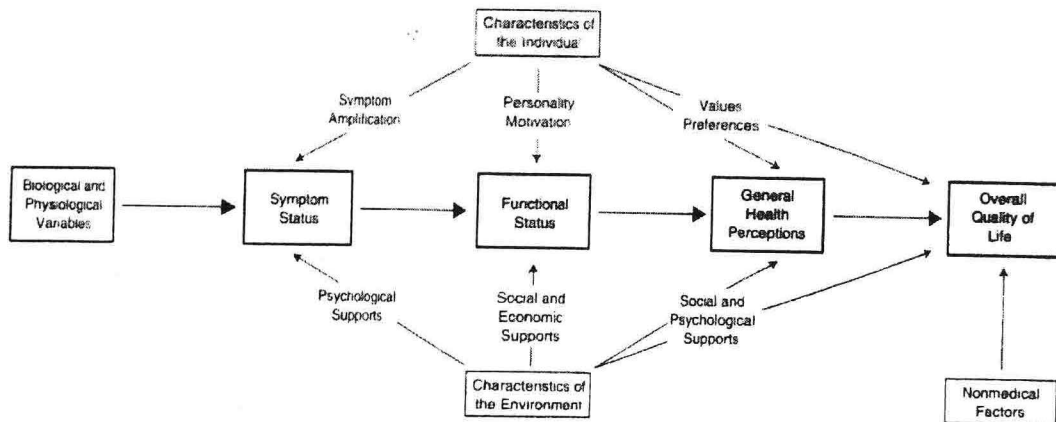


Figure 1. Wilson and Cleary's (1995) Health-Related Quality of Life Conceptual Model

Assumptions

The following assumptions were made:

1. Participants can read and understand the study instruments.
2. Participants will respond honestly to the study questionnaires.

Research Questions

Research questions for this proposed study include the following:

1. Are there differences in self-reported health status and HRQOL of men and women with a diagnosis of CHF?
2. Are there differences in age, race/ethnicity, living status, number of comorbidities, perceived general health status, and perceived symptom management of men and women with a diagnosis of CHF?

3. Are gender, age, race/ethnicity, number of comorbidities, living status, perceived general health status, perceived physical health status, perceived mental health status and perceived symptom management significant predictors of HRQOL?
4. Do symptom status (i.e., perceived symptom management), functional status (i.e., living status, perceived physical health status and perceived mental health status), and general health perceptions (i.e., perceived general health status) serve as mediating variables between the exogenous variables (i.e., gender, age, race/ethnicity, and comorbidity) and overall quality of life.

Definition of Terms

Age

Age is defined as the time, in years, from birth to the present year (Taber's Cyclopedic Medical Dictionary, 2005). Operationally, age will be the individual's self-reported age in years.

Ethnicity/Race

The conceptual definition of ethnicity/race is defined as "of or relating to large groups of people classes according to common racial, national, tribal, religious, linguistic, or cultural origin or background" (Merriam-Webster Online Dictionary, 2006, p. 1). The operational definition will be the respondent's answer(s) on the General Information Form (GIF) to ethnic identification: American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Not Hispanic or Latino, Native Hawaiian or Other

Pacific Islander, and White.

Living Status

Living status is defined as whether the individual lives alone, lives with someone, or lives in a residential setting. The operational definition is the participant's choice of one of these on the GIF.

Perceived General Health Status

Perceived general health status is defined as the individual's perceptions of how he or she views his or her health status. Operationally, the participant will choose one of the following categories on the SF-36v2: excellent, very good, good, fair, or poor.

Perceived Symptom Management

Perceived symptom management is defined as individuals' perceptions of how their symptoms are being managed or controlled as related to their heart failure.

Symptom management will be measured by a one-item Likert-type rating scale on the GIF, from 1 (symptoms not being managed well at all) to 10 (symptoms being managed extremely well). The higher the score, the better the symptom management.

Number of Comorbidities

Number of comorbidities is defined as the individual's self-report of how many different disease diagnoses he or she has. The participant will choose from the following diseases listed on the GIF: heart disease, high blood pressure, lung disease, diabetes, ulcer or stomach disease, kidney disease, liver disease, anemia or other blood disease,

cancer, depression, osteoarthritis, degenerative arthritis, back pain, rheumatoid arthritis, thyroid disease, obesity, and autoimmune disease. An option of “other” will also be provided.

Health-Related Quality of Life with CHF Diagnosis

The conceptual definition of HRQOL with CHF is defined as “the relationship between two concepts, health or disease (in this case heart failure) and QOL” (A. Brown, personal communication, July 12, 2006). The operational definition of QOL will be measured using the Minnesota Living with Heart Failure Questionnaire (MLHFQ). The MLHFQ is a QOL instrument specifically for heart failure patients. This questionnaire consists of 21 questions. Persons may respond to each question using a 6-point Likert-type scale where 0 = “no,” 1 = “very little,” and 5 = “very much.” On the original scoring instructions, the lower the score, the better the QOL; a higher score represents a poorer QOL. However, for the purpose of this research study the scoring was recoded so that the higher the scoring indicates the better the QOL.

Health Status

The conceptual definition of health status is “an overall evaluation of an individual's degree of wellness or illness with a number of indicators, including quality of life and functionality” (Ware, Kosinski, & Dewey, 2002, p. 10). The SF-36v2 is a 36-item instrument used to measure the two components of physical and mental health status. It also yields 8 profile scores. The SF-36v2 items and subscales (i.e., components) are scored so that a higher score indicates better health status.

Limitations

Participants' knowledge of the study's purpose may influence their responses to the questionnaires, thus altering the study results. Another limitation is related to the use of a cross-sectional study design which will only capture how the person feels at the time of instrument completion.

Delimitations

Participants will have a medical diagnosis of CHF and be attending one of two clinics for treatment. This study will use only English versions of the instruments; thus, reading English is a requirement for study participation.

Summary

This chapter provided an introduction to the chronic disease of CHF and some of the issues associated with it. The problem of the study and rationale for the study were identified. Little is known about the difference between men and women's responses to CHF or about the factors that predict their quality of life. An overview of the conceptual framework that will guide the study was presented. Assumptions, research questions and definition of terms were identified. Finally, limitations and delimitations were noted.

CHAPTER II

REVIEW OF THE LITERATURE

An increase in hospitalizations and mortality in congestive heart failure (CHF) patients has led researchers to examine health-related quality of life (HRQOL) and health status in patients who suffer from this disease. Hospital discharges for CHF increased from 399,000 in 1979 to 1,093,000 in 2003, an increase of 174%. In 2003, there were 2.4 million males and 2.6 million females with CHF, and the mortality during that year from CHF was 22,300 for males and 34,900 for females (American Heart Association [AHA], 2006). The effects of CHF are progressive and lead to reduced health status and quality of life. Thus, the purpose of this literature review is an ongoing review to examine research studies that link certain characteristics to health status and HRQOL. Reviewing the literature and finding areas where further research is needed will lay the foundation for this research study.

Historical Review of Gender Differences

Historically, research studies in the medical field have been predominantly conducted on men. The knowledge gained by this study will help healthcare providers understand and create evidence-based nursing interventions to improve health status and HRQOL acknowledging gender differences.

A brief historical perspective of men and women within the medical literature will be reviewed. In the first section gender differences will be discussed, followed by quality

of life and health status in CHF. Predictors of health status and quality of life will be discussed. A summary and implications of the findings will be discussed.

An exhaustive literature review was performed. Materials, both printed and electronic were utilized from the published literature of nursing, medicine, mental health, and psychology in the last five years. Databases that were used in the search were CINAHL, EBSCO, OVID, Proquest, PubMed, MEDLINE, and Web of Science. The following guidelines were used to select the literature for review:

1. A 5-year span (2001 – 2006) of research literature was utilized.
2. The literature review included national and international studies of health status and quality of life in CHF patients.
3. Only research articles written in or translated to English were used.
4. Literary search keywords were: “Congestive Heart Failure,” “CHF,” “Heart Failure,” “HF, cross-referenced with “health-related quality of life,” “HRQOL,” “quality of life,” “QOL,” “health status,” “gender differences,” “sex differences”, “age,” “gender,” “ethnicity,” “race,” “living status,” “comorbidity,” “New York Heart Association functional status,” “NYHA functional status,” “perceived NYHA functional status,” “perceived functional status,” and “perceived symptom management.”

Up to and during the late 1950s to the mid-1960s, women were associated with nurturing and caring, but were subordinate to men in status. The emphasis was placed on the health and fitness of men, who were known for comprising the primary work force and serving as sole provider for the family. Women were viewed as caretakers of others and, therefore, seen to be of lesser value (Miller & Kollauf, 2002).

Before 1986, issues concerning women's health focused on reproduction. The male population dominated cardiac research. Men were viewed as the standard by which to measure all people. Beginning in 1986, the National Institutes of Health (NIH) required that women be included in funded studies unless researchers provided adequate justification for not including them. Following that regulation, federal legislation insisted that all funding agencies include women and other underrepresented groups in funded studies. Finally, the NIH Revitalization Act of 1993 required that all funding by the NIH include both sexes (Miller & Kollauf, 2002). This Act gave NIH the ability to deny federal funding to proposed studies that excluded women without adequate justification.

Until the last decade, the literature that included women was more likely to discuss how they could best manage the care of their husbands' heart disease. Women have been significantly underserved and overlooked concerning heart disease. Following the NIH actions to promote the inclusion of women study participants, the literature reporting studies involving women with heart disease has increased, reflecting the change in standards of care (i.e., procedures, medications, and treatments) for women with heart disease today (Banks, 2008; Bundy, Gonzalez, Barnard, Hardy, & DuPont, 2006; Efre,

2004; Guru, Fremes, Austin, Blackstone, & Tu, 2006; Hussey & Hardin, 2003; Miller, 2002). This is reflected in Table 1.

Cardiac care and treatment is being provided to millions of women each day with treatments that were originally established for men from previous studies conducted only on men. Also, there have been few studies conducted on differences between the different cultures. This deficiency in cultural differences related to cardiac disease continues (Correa-de-Araujo, Stevens, Moy, Nilasena, Chesley, & McDermott, 2006; Miller, 2002).

Table 1

Summary of Gender Differences Studies

Author(s)	Number of Subjects/Sample	Type of Design	Method of measuring variables	Key Findings
King (2002)	Convenience sample N=24 participants (12 men, 12 women)	Qualitative	Interviews	Illness was due to stress in both genders Men stated behavioral or lifestyle as factors of illness onset. Women stated smoking or diet as influential to illness. Women were in the lowest socio-economic group.

Table 1 (Continued)

Summary of Gender Differences Studies

Author(s)	Number of Subjects/Sample	Type of Design	Method of measuring variables	Key Findings
Miller (2002)		Integrative Literature Reviews and Meta-Analyses		Women have many symptoms during an acute myocardial infarction (AMI): chest pain, fatigue, shortness of breath (SOB), back pain, edema, and transient non-specific chest discomfort.
Ng, Tam, Man, Cheng, and Chiu (2003)	N=94 participants (44 males 50 females)	Quantitative	Chinese Adult Source of Self-Esteem Inventory (ASSEI) Questionnaire	Women with cardiac disease found both personal and interpersonal life aspects to be higher than men. Women had a higher life satisfaction than men in appearance, grooming, and popularity.

Table 1 (Continued 2)

Summary of Gender Differences Studies

Author(s)	Number of Subjects/Sample	Type of Design	Method of measuring variables	Key Findings
Devon and Zerwic (2003)	N=100 participants (50 women, 50 men)	Nonexperimental, exploratory, descriptive quantitative design	Unstable Angina Symptoms Questionnaire (UASQ) Canadian Cardiovascular Society (CCS) Classification of Angina Hospital Anxiety and Depression Scale (HADS)	Women experience more SOB, weakness, difficulty breathing, nausea, and loss of appetite than men. Women had more upper back pain, stabbing pain, and knife-like pain. Women were more likely to experience depression.
Bundy, Gonzalez, Barnard, Hardy, and DuPont (2006)	N=3,878 patients (957 females, 2921 males)	Retrospective epidemiologic cohort study	Retrospective review	Women had a greater risk of having surgical site infection (SSI) than men. Predictors of acquiring SSI were being female, diabetes, BMI, and urgency of surgery.

Table 1 (Continued 3)

Summary of Gender Differences Studies

Author(s)	Number of Subjects/Sample	Type of Design	Method of measuring variables	Key Findings
Guru, Fremes, Austin, Blacksone, and Tu (2006)	N=66,193 patients (14,393 females, 51,800 males)	Retrospective cohort study	Retrospective review using four databases	<p>Women were older, were urgent or acute emergency status, and arterial grafts were not often used.</p> <p>Women had a higher 1 year cardiac readmission rate following surgery; that rate continued after 1 year.</p> <p>Readmissions were due to CHF and unstable angina.</p>

Empirical Studies of Gender Differences

Within the literature, gender differences have been the focus of several research studies (see Table 1). The Table is followed by a brief summary of each publication.

King (2002) conducted a qualitative study on illness attributions involving 24 men and women diagnosed with a myocardial infarction. Findings from the study revealed that both men and women agreed that stress was a cause of their illness. Men believed that stress resulted from work-related factors, while women believed that their stress was secondary to relationship issues. Women were more likely to have a lower socioeconomic status and voiced a concern of decreased autonomy and self-efficacy following a myocardial infarction.

Miller (2002) conducted a literature review of symptoms that women have with coronary artery disease. She searched the literature from 1995 to 2000 using CINAHL and Medline. Results of studies located from this search demonstrated that women had symptoms such as nausea, bloatedness, fatigue, dizziness, and shortness of breath. Women did have chest pain, although it was perceived by them as not significant and/or was not necessarily the first symptom to appear. Women most often did not seek medical care for symptoms of heart failure.

Ng, Tam, Man, Cheng, and Chiu (2003) conducted a study examining gender differences in self-esteem in Hong Kong Chinese population with cardiac disease. Forty-four males and 54 women who had been diagnosed with cardiac disease for 1 year or longer participated in this study. Analysis of the Adult Source of Self-Esteem Inventory (ASSEI) questionnaire revealed women under the age of 60 demonstrated better adjustments than men, including QOL. The authors found that this study contained cultural uniqueness.

Devon and Zerwic (2003) conducted a descriptive study on gender differences in symptoms of unstable angina. A convenience sample of 50 men and 50 women participated in the study. Ages for women ranged from 41-88 years ($M = 64.88$, $SD = 11.88$) and men ranged from 35-85 years ($M = 61.44$, $SD = 11.51$) with no statistical significance. Shortness of breath, weakness, difficulty breathing, nausea, and loss of appetite were experienced significantly ($p < .05$) more often by women than men. Women continued to have weakness ($p = .03$), difficulty breathing ($p = .02$), nausea ($p = .03$), and loss of appetite ($p = .02$) after controlling for age, diabetes, anxiety, depression and functional status. Women reported more upper back pain, stabbing pain, and knife-like pain ($p < .05$). They also experienced a significantly higher occurrence of depression ($p < .01$).

Bundy, Gonzalez, Barnard, Hardy, and DuPont (2006) conducted a retrospective epidemiologic study of gender risk differences linked to postoperative coronary artery bypass graft (CABG) surgical site infections. There were 957 (24.7%) women and 2921 (75.3%) males who had significant differences prior to surgery for characteristics of age, body weight, and height ($p < .0001$). On an average, women were older by 4 years, were 35 pounds lighter, and 6 inches shorter in height. Results of the study found that women had a significantly higher incidence of postoperative CABG nosocomial surgical site infections (SSI) ($p = .004$) than men. Women had a higher occurrence of urgent surgeries and emergency procedures than men, as well as a higher incidence rate of surgical site infections at the chest and leg sites. A study limitation was that the patient population was from only one institution.

Guru, Fremes, Austin, Blackstone, and Tu (2006) explored gender differences in outcomes after hospital discharge in patients who had undergone a CABG. The study used the Cardiac Care Network database (September 1, 1991 and March 31, 2002). Of the 66,193 patients, 51,800 (78%) were males and 14,393 (22%) were females. Women were older, had a lower socioeconomic status, and had more comorbidities than men. Arterial grafts were not used in women as often as in men, and women received fewer numbers of grafts regardless of their presenting coronary disease status. The study found that women were much more likely to have either early cardiac readmission (≤ 1 year) or late cardiac readmission (> 1 year) following CABG; however, they were not as likely to die after discharge following CABG surgery. Readmissions for strokes were more often seen in women than men; however, after risk adjustment, men were slightly higher than women. Men had a higher repeat revascularization than did women; however, after risk adjustment, there was not a significant difference statistically. Preoperatively, women had better ventricular function than men, however, they were found to have higher readmission rates for CHF.

Quality of Life and Health Status in Congestive Heart Failure

Health status and quality of life have been studied within the cardiac literature. These two concepts can reflect a person's perception of their perceived health status. A summary of health status and HRQOL studies is provided in Table 2, and discussion of these studies follows.

Table 2

Summary of Health Status and HRQOL Studies

<i>Author(s)</i>	<i>Subjects</i>	<i>Type of Design</i>	<i>Method of measuring variables</i>	<i>Key Findings</i>
Conard, Heidenreich, Rumsfeld, Weintraub, and Spertus (2006)	N=539 patients	Prospective cohort quantitative study	<p>Kansas City Cardiomyopathy Questionnaire (KCCQ)</p> <p>Short Form-12 (SF-12) questionnaire</p> <p>Medical Outcomes Study-Depression (MOS-D) questionnaire</p> <p>Question asked for economic burden</p> <p>Brain natriuretic peptide (BNP)</p>	Patients who perceived to have economic burden had poorer health status

Table 2 (Continued)

Summary of Health Status and HRQOL Studies

<i>Author(s)</i>	<i>Subjects</i>	<i>Type of Design</i>	<i>Method of measuring variables</i>	<i>Key Findings</i>
Morgan et al. (2006)	N=522 patients	Quantitative Study	Question for difficulty taking medications (5-level Likert scale) MOS-D questionnaire KCCQ	Patients who had difficulty taking medications had poorer health status and greater depressive symptoms. These relationships weaken once demographic and clinical factors were adjusted.
Soto, Jones, Weintraub, Krumholz, and Spertus (2004)	N=1516 (401 females, 1115 males)	Prospective, international cohort quantitative study	KCCQ	The greater the HRQOL there was an 84% 1-year event-free of cardiovascular mortality and hospitalization.
Juenger et al. (2002)	N=205	Quantitative Study	New York Heart Association (NYHA) functional class SF-36 questionnaire	As the NYHA functional class increases (functional class becomes worse) the QOL decreases.

Table 2 (Continued 2)

Summary of Health Status and HRQOL Studies

<i>Author(s)</i>	<i>Subjects</i>	<i>Type of Design</i>	<i>Method of measuring variables</i>	<i>Key Findings</i>
Riedinger et al., 2002	N=691 women from SOLVD trials	Secondary Analysis	Profile of Mood States Inventory (POMS) Functional Status Questionnaire (FSQ) Beta Blocker Heart Attack Trial instrument Symptoms Scale Ladder of Life RAND Medical Outcomes Study instrument	Women with CHF have a poorer QOL, vigor, activities of daily living, social activity, and ratings for general health as compared to a normative group. Women with CHF had greater levels of anxiety and depression as compared to a normative group.

Table 2 (Continued 3)

Summary of Health Status and HRQOL Studies

<i>Author(s)</i>	<i>Subjects</i>	<i>Type of Design</i>	<i>Method of measuring variables</i>	<i>Key Findings</i>
Clark, Tu, Weiner, & Murray, 2003	N=212 patients	Randomized controlled trial	KCCQ Chronic Heart Failure Questionnaire (CHQ) Single question asking about perceived health NYHA classification tool Charlson Index Income satisfaction Social support Health Belief Scale (HBS) Short Test of Functional Health Literacy in Adults	Greater age, males, and African-American participants stated better HRQOL. Positive health beliefs, higher income, social support, and patient-physician communication demonstrated increase HRQOL

Table 2 (Continued 4)

Summary of Health Status and HRQOL Studies

<i>Author(s)</i>	<i>Subjects</i>	<i>Type of Design</i>	<i>Method of measuring variables</i>	<i>Key Findings</i>
Rodriguez-Artalejo et al. (2005)	N=394 patients (221 females, 173 males)	Prospective, quantitative study	Biomedical and psychosocial variables Medical Outcomes Study 36-Item Short Form (SF-36) questionnaire Minnesota Living with Heart Failure Questionnaire (MLWHF)	Poorer SF-36 scores (worse health status) indicated higher frequency of hospital readmissions. Higher MLWHF scores (poorer HRQOL) indicated a higher mortality.
Bosworth et al. (2004)	N=15 male patients	Cross-sectional qualitative study	Focus Groups	Five domains: symptoms, role loss, affective response, coping, social support. Patients were concerned with physical and cognitive function. Patients expressed a concern for family and the uncertainty of the illness on their mortality.

Table 2 (Continued 5)

Summary of Health Status and HRQOL Studies

<i>Author(s)</i>	<i>Subjects</i>	<i>Type of Design</i>	<i>Method of measuring variables</i>	<i>Key Findings</i>
Rhodes and Bowles (2002)	N=5	Phenomenological qualitative study	Semi-structured interviews	Four main themes: "Acknowledging losses in their lives," "accepting the losses," "changing their lives," "deepening relationships"

CHF has had an economic impact on patients and their medical costs. Conard, Heidenreich, Rumsfeld, Weintraub, and Spertus (2006) conducted a cross-sectional, longitudinal study (one year) of perceived economic burden and health status of 539 patients. At baseline, 238 (44%) of the patients thought that their medical costs were creating a considerable financial burden. Those with economic burden were noted to be younger (59.5 ± 23.6) as compared to those who did not perceive economic burden (63.6 ± 23.5 , $p = .001$) and whose income was greater than \$30,000 per year ($p < .001$). The Kansas City Cardiomyopathy Questionnaire (KCCQ) summary score was significantly lower in patients who perceived economic burden ($p = .001$), meaning that patients who demonstrated a lower disease-specific health status had greater economic burden. Progressively worse health status was demonstrated by Likert-type responses which were significant ($p < .001$). For generic health status and economic burden, patients who perceived that they had economic burdens reported more physical limitations ($p = .001$)

and worse mental health ($p = .001$). During an assessment of participants one year following baseline, their difficulty affording health care was greater and their health status was significantly ($p = .002$) lower.

Morgan et al. (2006) conducted a study related to the difficulty of taking medicine with 522 CHF patients. Sixty-four (12.2%) patients stated that they had difficulty taking their prescribed medications, while 458 (87.7%) did not. Those who had difficulty taking their medication were noted to have a significant increase in heart failure symptoms, increase in social limitation, decrease in self-efficacy, and decrease in quality of life ($p > .05$ for each subscale). Symptoms of depression were significantly higher ($p < .01$) in patients who had difficulty taking their medication (43.8%) as compared to patients who had no difficulty taking medications (27.1%). Symptoms of depression were also greater ($p < .001$) in those with decreased health status.

Soto, Jones, Weintraub, Krumholz, and Spertus (2004) conducted a study of 1516 acute myocardial infarction (AMI) patients using the Kansas City Cardiomyopathy Questionnaire (KCCQ) which measures disease-specific health status. Seventy-three percent ($n = 1115$) were male and 26.4% ($n = 401$) were female. There was a strong association with cardiovascular events and scores of ≥ 75 were noted to have an 84% 1-year event-free survival versus 59% in scores < 25 ($p < .001$).

An outcome measure seen in many research studies is quality of life (QOL) (Brubaker, Witta, & Angelopoulos, 2003; Juenger et al., 2002; Riedinger, Dracup, Brecht, Padilla, Sarna, Ganz, 2002). It is recognized as a key indicator of the effectiveness of medical treatment in women diagnosed with CHF. QOL varies as the

course of disease progresses and treatment regimens change. Individuals greater in age, male, and black were noted to have higher CHF-specific HRQOL scores (better HRQOL). This was also true of individuals who reported an increase in positive health beliefs, higher income, greater social support, and greater communication with their health care provider (Clark, Tu, Weiner, & Murray, 2003).

Rodriguez-Artalejo et al. (2005) conducted a study on HRQOL as a predictor of hospital readmission and death in heart failure patients. This study was conducted in four Spanish hospitals with 394 patients, 173 (43.9%) were males and 221 (56.1%) females. The authors reported a higher readmission rate for patients with lower scores (worse function) on the physical functioning ($p = .01$), general health ($p = .003$), and mental health ($p = .02$) subscales of the Medical Outcomes Study 36-Item Short Form (SF-36) questionnaire. Using the Minnesota Living with Heart Failure (MLHFQ) questionnaire, researchers found that there was a greater mortality rate with higher overall scores (worse HRQOL) along with higher physical and emotional scores (worse HRQOL). Individuals whose scores were higher than the median on the MLHFQ had a higher mortality, approximately 2 or more times greater, than observed in patients with lower scores.

Bosworth, Steinhauser, Orr, Lindquist, Grambow, & Oddone, (2004) conducted a qualitative study involving focus groups of 15 male patients with CHF, ranging in age from 47 to 82 years. The study examined patients' perceptions of quality of life involving physical and psychosocial characteristics. Five themes emerged: physical symptoms, role loss, affective responses, coping, and social support. In addition to these themes, concerns were identified by patients for their families, the uncertainty of their illness

and/or prognosis, and concern of their cognitive functions which all contribute to their QOL. The authors found that patients with CHF who developed adaptation and coping mechanisms to deal with their illness had potential personal growth.

Rhodes and Bowles (2002) conducted a phenomenological study involving 5 women and their experience of living with CHF. Ages ranged from 60 to 90 years of age. Semi-structured interviews were conducted with each of the participants. Acknowledging losses in their lives, accepting the losses, changing their lives and deepening relationships were the four main themes that emerged from the data. The authors noted that CHF affected every aspect of the women's' life, which led to changes within their day living. The women drew from their inner self for strength and courage to have productive lives while living with CHF.

Recent studies demonstrate that QOL affects patient's physical and mental health status. Furthermore, the social and economic impact of CHF also impacts patient's perception of their QOL. Gender and racial differences were discussed, along with hospital readmissions. Future investigations are needed to assess gender differences and interventions to improve QOL in individuals with CHF. The next section will discuss predictors on health status and QOL.

Predictors of Health Status and Quality of Life

This section of the literature review focuses on the demographic and personal characteristics of age, gender, race, living status, comorbidities, NYHA function status, and perceived symptom management. These are characteristics that affect health status and QOL.

Mejhert, Kahan, Persson, and Edner (2006) conducted a study with 208 CHF patients: 58% were male, and the mean age was 76. Of the 208 patients, 36% ($n = 74$) died and 82% ($n = 171$) had readmissions to the hospital. Independent predictors of mortality were age, male, elevated brain natriuretic peptide (BNP), mitral end point septal separation (EPSS), and creatinine level. Predictors of readmissions were poor QOL ($p < 0.001$).

Age is a variable that is discussed throughout studies conducted on CHF patients. Hou, Chui, Eckert, Oldridge, Murray, & Bennett (2004) conducted a study focused on age and sex as it relates to HRQOL in patients with CHF. There were 165 patients in the study; mean age was 57.6 years (range 26-85). Fifty-two percent were female and 48% were male. Sixty-two percent of females and 84% of males were less than 65 years of age. Interviews were conducted at baseline and 26 weeks later. At baseline, patients under 65 years of age had HRQOL scores that were poorer than did the older patients. Women had poorer HRQOL than men on some scales. During the 26th week, patients less than 65 years old had significantly worse HRQOL than patients' 65 years of age or older. During this same timeframe, women had significantly worse HRQOL than did men. Similar findings were found by Gottlieb et al. (2004) who reported that patients 64 years or younger had worse QOL.

In another study, Cowie et al. (2002) examined factors that predicted hospitalization and mortality. Mortality was linked to advancing age, increase in serum creatinine and a greater severity of symptoms noted during the first presentation to the

hospital. Age was the only independent predictor of the total time spent in hospital for readmissions during the follow-up time frame.

In a recent study, African-Americans were noted to have a higher incidence of delaying treatment among heart failure patients (Evangelista, Dracup, & Doering, 2002). Rathore et al. (2003) stated that African-American patients have an increase in readmission rates into the hospital.

According to Luttik, Jaarsma, Veeger, and van Veldhuisen (2006), most of the patients who were living alone were elderly women with low incomes. They also reported having a decreased QOL and were at risk for having recurrent hospitalizations as compared to those women who were married or living with someone. Hamner and Ellison (2005) reported patients living with family members, as opposed to living in a facility or living alone, were linked to hospital readmissions.

In the majority of studies reviewed it was noted that as the NYHA functional class score increased or heart failure worsened, the QOL decreased in patients with heart failure (Juenger et al., 2002; Riedinger, Dracup, Brecht, Padilla, Sarna, & Ganz, 2001).

In a qualitative study by Crowder (2006), patients with worsening symptoms of CHF noted increased mortality along with an increase in comorbidities. A study by Alfred, Gott, and Gariballa (2005) found that CHF had a significant negative impact on the patient's life as well as that of their partners. The participants and their partners felt as if symptoms associated with CHF were an isolating factor in their lives. The partner took on a role as supporter, maintained household tasks, and helped with physical care of the patient. In this study, symptoms such as fatigue and breathlessness had a physical impact

as well as a social one. This group of participants believed that the professional care their partner received was inadequate in coverage and was poorly coordinated.

In one study, patients who were depressed had a higher incidence of hypertension than those who were not depressed (Gottlieb et al., 2004). There are several research studies that indicate patients who have diabetes have a higher incidence of mortality associated with CHF (Bell, 2003; Bertoni, Hundley, Massing, Bonds, Burke, & Goff, 2004). A study by Clark, Tu, Weiner, and Murray (2003), however, found no significant association between comorbidity and any of the HRQL measures.

Shahar, Lee, Kim, Duval, Barber, and Luepker (2004) examined hospitalization and mortality examined, studying a total of 2887 hospital records that met the criteria for heart failure patients. The authors found that within 1 year of hospitalization, 37% (550/1472) of males and 30% (419/1415) of females had died. Five to 6 years after the initial hospitalization, the cumulative mortality was 72% for men and 66% for women. Hospitalization rate increased by age; there were a few dozen patients hospitalized per 100,000 residents from 35 to 44 years of age; the rate was 2000 patients per 100,000 for residents from 75 to 84 years of age. The hospitalization rate of men was 50% greater than that of women. They also found that heart failure patients have a higher mortality than the general population. Heart failure-related hospitalizations had at least 10,000 deaths per 100,000 and that increased to more than 30,000 per 100,000 in the elderly. Thus, on average heart failure-related hospitalizations had 10 times a mortality risk.

Yu, Lee, and Woo (2004) conducted a study of 227 elderly Chinese CHF patients and their health-related quality of life; 52.4% were female, and the mean age was 77.1

($SD = 7.9$; range: 60-95). The authors found that the health perception scores (i.e., a reflection of the patient's perceived health status) were generally low. A correlation matrix of HRQOL with a number of variables demonstrated the highest correlation to be with psychological distress ($r = -.58$). Other correlations in the matrix were health perception ($r = .50$), functional status ($r = -.40$), and perceived social support ($r = .35$), age ($r = -.20$), educational level ($r = .23$), presence of spouse ($r = .22$) and living condition ($r = .23$). However gender, income, length of time participants had suffered HF, number of medications, number of comorbidities, and hospitalization did not significantly relate to HRQOL. This study demonstrated that CHF patients who have increased psychological distress, poor health perception, increased functional impairment, or decreased perceived social support had decreased HRQOL.

Todero, LaFramboise, and Zimmerman (2002) conducted a study on QOL and symptom status with 93 CHF patients in a home-based disease management program. The average age was 70.5 ± 11.8 years (range was from 39 to 91 years of age). Eighty-four percent were Caucasian; 13%, African American, and 3%, other ethnicities. The authors found that as the QOL scores became better, so did the symptom status scores.

Bennett, Perkins, Lane, Deer, Brater, and Murray (2001) conducted a study with 147 CHF patients related to HRQOL and social support. There were 52% ($n = 117$) women and 48% ($n = 110$) men. Fifty-three percent ($n = 121$) were African-American and 47% ($n = 106$) were Caucasian. The mean age was 64 years ($SD = 12$); range in age was 27-92. Seventy-two percent of the patients were not married. Hypertension was the most common comorbid condition at 59%, followed by diabetes mellitus at 50%,

coronary artery disease at 39%, previous coronary artery bypass graft at 9%, myocardial infarction at 8%, and angina at 8%. The authors found that less support was found in men less than 65 years of age as compared to men 65 years of age or older or the women in either age group. Changes in HRQOL were directly related to changes in social support.

Age, lower income, readmission rates, NYHA functional status, comorbidities, gender, and ethnicity were found to play important roles in the health status and QOL of patients with CHF. Further studies of these and other possible predictors of health status and QOL are needed.

Summary

This chapter has reviewed the historical perspective of men and women in medical research. Until recent years, the majority of research has been on men; however, women have more recently been included and some gender differences identified. This is true concerning research specifically pertaining to CHF. Health status and quality of life are noted within the CHF population. Predictors of health status and HRQOL were reviewed. Key points from the literature are summarized below:

1. Women are more likely to have lower socioeconomic status.
2. There are gender differences (e.g., older women being more physically impaired than older men, women have worse QOL ratings than did men for intermediate activities of daily living and social activity) in research studies.
3. The worse the HRQOL or health status, the higher the risk of mortality and re-hospitalization.
4. Patients with economic burden had a poorer health status.

5. Patients who had problems taking their medications had a poorer health status and had an increase in depressive symptoms.
6. The higher the NYHA function class score, the poorer the HRQOL and health status in patients with CHF.
7. Women with CHF when compared to normative groups had poorer QOL, vigor, activities of daily living, social activity, and ratings for general health; levels of anxiety and depression were greater.
8. Positive health beliefs, higher income, social support, and better patient-physician communication were associated with greater HRQOL.
9. CHF patients expressed concerns about their cognitive, physical, and psychosocial functioning.

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

The purpose of this study was to examine the health status and HRQOL of men and women with a diagnosis of congestive heart failure (CHF). The procedure describes the research study's design, sample and setting, protection of human subjects, instruments, data collection, and treatment of the data.

Research Design

This study used a cross-sectional exploratory design which examined groups of participants at a certain moment in time (Burns & Grove, 2005; Polit & Beck, 2008). Incorporating correlational techniques allowed the researcher to explore relationships among variables (Polit & Beck).

Sample and Setting

The non-probability, convenience sample ($N = 113$) included 76 men and 37 women with a diagnosis of CHF who were attending a CHF clinic for treatment. Inclusion criteria for this study included (a) a diagnosis of CHF, (b) 18 years of age or older, and (c) the physical and mental ability to complete the questionnaire packet. Exclusion criteria included (a) any history of a surgical procedure within the last 3 months, (b) history of starting on a new beta blocker medication within the last 3 months, and (c) any history of hospitalization within the last 6 weeks.

Recruitment began with flyers placed in designated cardiology clinics to notify patients of the research study. Individuals 18 years and older diagnosed with CHF let the clinic receptionist know if they were interested in participating in the study. Once patients had expressed an interest in the study to the receptionist, either the principal investigator (P.I.) or the nurse liaison met with the patient on that day in a designated private room or in a sitting area, whichever was agreed upon by the patient and investigator or nurse liaison. The study was explained and the patient was invited to participate if the inclusion and exclusion criteria were met.

Data Collection

After the informed consent had been signed by participants, they were given the instrument packet. Instruments included (a) the General Information Form (GIF) to collect demographics and health-related information; (b) the Medical Outcomes Study Health Survey, Version 2.0 (SF-36v2™) for assessing the perceived physical and mental health status; and (c) the Minnesota Living With Congestive Heart Failure® (MLHFQ) questionnaire for assessing health-related quality of life (HRQOL). The P.I. or nurse liaison remained available to answer any questions the participant may have had and to collect the completed forms. Participants were instructed not to put their names on the forms that were prenumbered. The participant received a copy of the consent form. The completed consent forms and tests were placed in a numbered folder and sealed. The P.I. or nurse liaison placed the folder in a locked filing cabinet in the clinic; at least bi-monthly it was transported from the clinic area to the P.I.'s office where it was placed in a locked file drawer. The P.I. separated the consent forms and completed questionnaires

into different folders before storing them. Data were then entered for statistical analysis by the P.I. using SF-36 Health Outcome scoring software and SPSS Graduate Pack version 11.0 for Windows. The dataset used only the identification (I.D.) number; no identifiable information was used.

At least 113 participants were recruited through nonprobability sampling. The sample size was based on the formula $N \geq 104 + k$ where k was the number of independent variables ($n=9$) in the model that was tested using multiple regression (Newton & Rudestam, 1999). This rule assumes an alpha level of .05, a power of .80, and a medium effect size (Arslanian-Engoren, 2001). This number was also appropriate for examination of gender differences in health status and HRQOL (Garson, 2008; VanVoorhis & Morgan, 2001).

Protection of Human Subjects

Prior to data collection, approval was obtained from Texas Woman's University (TWU) Institutional Review Board (IRB). During the course of this research study, confidentiality of participants' information was maintained. All records were coded with a number used only for organizing the data. No names appeared on any papers. The purpose of the study was explained and the opportunity to ask questions was provided. Participants were assured that their participation was voluntary and that they could withdraw their participation at any time. The completed forms were stored in a locked file cabinet in the investigator's office.

Instruments

Medical Outcomes Study Health Survey, Version 2.0 (SF-36v2™)

The SF-36v2 is a 36-item instrument used to measure physical and mental health status. The survey yields an 8-subscale profile of scores. Physical and mental health summary measures are provided. Individual scores are also provided for each of the 8 subscales: (physical functioning {PF}, role-physical {RP}, bodily pain, {BP}, general health {GH}, vitality {VT}, social function {SF}, role-emotional {RE}, mental-health {MH}). The SF-36 is a generic tool for measuring health status that can be used with any disease process (Ware, nd).

Scoring for Analysis

The SF-36v2 uses norm-based scoring algorithms for all scales. The scoring software for version 2 was used. The scores were scaled from 0 to 100. For items missing on a subscale, simple mean imputation was performed. This consisted of only 3 cases. If a physical or mental health status score could not be computed due to data not being available, a simple mean imputation was used as it related to the person's gender and racial status. This consisted of only one case. The SF-36v2 items and scales were scored so that a higher score indicated better health status.

Administration

The instrument response format is designed for self-report. Approximately 10 to 15 minutes was needed to complete the health status questionnaire.

The SF-36 was developed for individual measurement as well as for group comparisons. The eight concepts comprising the SF-36 were derived from the Medical Outcomes Study (MOS) which had 37 total concepts (Ware, nd). All but one of the 37 items was used. From the 36 concepts, eight main concepts were formed. The eight concepts were derived from health surveys which were well known within the literature and were seen as having effects on diseases and the treatment of these diseases (Ware, 1995; Ware, Snow, Kosinski, & Gandek, 1993).

The SF-36 was designed from instruments dating back to the 1970s and 1980s (Stewart & Ware, 1992). Some of the items were from the General Psychological Well-Being Inventory (GPWBI), physical and role functioning measures from various tools, the Health Perceptions Questionnaire (HPQ), and other measures from the Health Insurance Experiment (HIE; Ware, nd). In 1992, the Functioning and Well-Being Profile (FWBP) was developed using previous questionnaire items and new measures (Stewart & Ware, 1992). This tool was the primary influence for the SF-36 questionnaire. The SF-36 was in the developmental stage during 1988 and the final form became available in 1990 (Ware, 1988; Ware & Sherbourne, 1992).

The second version of SF-36 was created in 1996. Changes made from the original version stemmed from studies in qualitative and quantitative research (Ware, Kosinski, & Dewey, 2000). Changes in the questionnaire included: (a) simplification and shortening of wording, (b) larger type-size, (c) better translation and cultural adaptations,

(d) five-level response choices in the two role functioning scales, and (e) five-level response categories in the Mental Health (MH) and Vitality (VT) scales (Ware, n.d).

Validity and Reliability

The SF-36 questionnaire has well known psychometric properties and those reported for several studies are mentioned below and summarized in Table 3. Internal consistency and test-retest methods were used to test reliability of the eight scales and two summary measures. The literature has shown reliability statistics exceeding the minimum standard of 0.70 in more than 25 studies (Tsai, Baylis, & Ware, 1997). Many of these studies have exceeded 0.80 (McHorney, Ware, Lu, & Sherbourne, 1994; Ware, Snow, Kosinski, & Gandek, 1993). Content, concurrent, criterion, construct, and predictive evidence of validity have been documented in the literature using the SF-36 questionnaire.

Cleary, Epstein, Oster, Morrissey, Stason, and Debussey (1991) had an internal consistency with a coefficient alpha of .84 or greater for each scale at baseline in approximately 500 patients undergoing percutaneous transluminal coronary angioplasty (PTCA). Weinberger, Samso, Hanlon, Schmader, Doyle, and Cowper (1991) evaluated the health status of 25 elderly male veterans using the SF-36. The reliability correlation coefficient was .78 for physical function, .67 for social function, and .73 for overall function. The researchers found that the shorter administration time of this instrument was a positive feature. Nerenz, Repasky, Whitehouse, and Kahdonen (1992) used the SF-36 with 235 diabetic patients. The test-retest correlations between baseline and six months ranged from 0.60 to 0.90. A study was conducted by Kurtin, Davies, Meyer,

DeGiacomo, and Kantz (1992) of 39 outpatients who received hemodialysis. The internal-consistency reliability estimates during first-time administration ranged from 0.62 to 0.90. Brazier et al. (1992) conducted a study with 1980 patients using the SF-36 instrument. Reliability of the instrument was measured using internal consistency which resulted in Cronbach's alphas ranging from .73 to .96. Reliability coefficients ranged from .74 to .93 (p. 162). Stability of the instrument's subscales was measured using test-retest reliability at two weeks. For all dimensions, 91-98% of cases lay within the 95% confidence interval constructed for a normal distribution (p. 162).

Construct validity was demonstrated in a study by Brazier et al. (1992) by scores reflecting what might be expected. For example, the lower social class group participants demonstrated poorer health status in all dimensions ($p < .05$) except for general health perception. Poorer perceived health status was seen in patients who had consulted their general practitioner two weeks prior to testing than those patients who had not. Convergent and discriminant validity were satisfied by using correlation coefficients with the SF-36 and Nottingham health profile. Correlation coefficients for four comparable dimensions of the SF-36 questionnaire and Nottingham health profile were higher than correlations between non-comparable dimensions (p. 162). The SF-36 was able to detect low levels of illness along with the Nottingham scoring low which reflected good health (Brazier et al.).

Katz, Larson, Phillips, Fossel, and Liang (1992) conducted a study of 106 patients who underwent hip surgery. Convergent validity was estimated to be high ($r = .78$) when the SF-36 was correlated with the Sickness Impact Profile (SIP). McHorney, Ware, Lu,

Table 3

Reliability and Validity Estimates of the SF-36

Study	Sample Size	Psychometric Properties
Cleary, Epstein, Oster, Morrissey, Stason, & Debussey (1991)	500 patients undergoing PTCA at baseline	Cronbach's alpha = .84 or greater for each of the scales
Weinberger, Samsa, Hanlon, Schmader, Doyle, & Cowper (1991)	25 elderly, male veterans	Correlation coefficient = .78 (physical), .67 (social) and .73 (overall)
Nerenz, Repasky, Whitehouse, & Kahkonen (1992)	First cohort = 117 patients Second cohort = 116	Test-retest correlations = .60 to .90; except pain scale = .43
Kurtin, Davies, Meyer, DeGiacomo, & Kantz (1992)	39 hemodialysis out-patients	Internal-consistency = .62 to .90
Brazier et al. (1992)	1582 patients – first survey Repeat test 187	Cronbach's alpha = .73 to .96 Reliability coefficients = .74 to .93 Test retest = .60 to .81 Construct validity = acceptable Convergent and discriminant validity = acceptable
Katz, Larson, Phillips, Fossel, & Liang (1992)	106 hip surgery patients	Correlations = .78

Table 3 (Continued)

Reliability and Validity Estimates of the SF-36

Study	Sample Size	Psychometric Properties
McHorney, Ware, Lu, & Sherbourne (1994)	3,445 patients and 24 subgroups	Item-internal consistency = 97% Item-discriminant validity = 92% Reliability coefficients = .65 to .94

and Sherbourne (1994) conducted a study using the SF-36 with 3,445 patients and 24 subgroups including different sociodemographic characteristics and diseases. Item-internal consistency was 97% and item-discriminant validity was 92%. Reliability coefficients ranged from .65 to .94 across all scales with variations across patient subgroups. A summary of reliability and validity of the SF-36 is in Table 3.

Minnesota Living with Congestive Heart Failure®

The Minnesota Living With Congestive Heart Failure® (MLHFQ) is a quality of life (QOL) instrument specifically for heart failure patients. This questionnaire consists of 21 questions. Persons may respond to each question using a 6-point Likert-type scale where 0 equals *no*, 1 equals *very little*, and 5 equals *very much*.

Scoring for Analysis

The MLHFQ is scored by summing the responses to the 21 questions. A physical dimension score can be calculated by summing items 2, 3, 4, 5, 6, 7, 12, and 13. An emotional dimension score can be calculated by summing items 17, 18, 19, 20, and 21. The remaining 8 questions asked the following questions: Did your heart failure

prevent you from living as you wanted during the past month (4 weeks) by (a) causing swelling in your ankles or legs; (b) making your working to earn a living difficult; (c) making your recreational pastimes, sports or hobbies difficult; (d) making your sexual activities difficult; (e) making you eat less of the foods you like; (f) making you stay in a hospital; (g) costing you money for medical care; and (h) giving you side effects from treatments? All items were included in the total score. The lower the score, the better the QOL. However, during data analysis, a decision was made by the researcher to reverse the scores so that the data would be interpreted in the same manner as the SF-36v2; thus, the higher the score, the better the quality of life.

Administration

The instrument response format is designed for self-report. Approximately 10 minutes was needed to complete the questionnaire.

Form Development

The MLHFQ was developed in 1984 to specifically measure a person's quality of life when living with heart failure and the treatments that are involved. The questionnaire was designed to represent heart failure and treatments and their effects on a person's physical, emotional, social, and mental dimensions of quality of life. Physicians and nurses treating and caring for patients at the University of Minnesota were involved in developing questions that affected the QOL of patients with heart failure (Rector, 2005).

Validity and Reliability

The MLHFQ is a valid and reliable instrument. Rector, Francis, and Cohn (1987) constructed a questionnaire named the Sickness Impact Profile which was administered

to 45 individuals with CHF. This questionnaire demonstrated poor correlation with maximal exercise tests. In 1987, a new questionnaire was developed, the Minnesota Living with Heart Failure Questionnaire (Rector, Francis, & Cohn, 1987). A primary list of questions was generated by patients with CHF from the Sickness Impact Profile. From this list, questions specifically addressed by patients with CHF were then selected to form a new, shorter set of questions which were chosen to be used in the MLHFQ. Internal consistency was acceptable with correlations of .35 to .86. Reliability of the instrument was measured by the differences between the two baseline scores and reproducibility was measured using weighted kappa. There was a weak relationship (Spearman's $r = -.34$, $p < .01$) seen in the differences between the two baseline scores and the weighted kappa for reproducibility for both scores were .84. Validity of the instrument was noted in the high correlation ($r = .80$, $p < .01$) between the MLHFQ score and the patient's perception of global health as it relates to their heart failure as measured by the question "Overall, how much did your heart failure prevent you from living as you wanted during the last month?" (p. 205) The New York Heart Association (NYHA) classifications correlated with the MLHFQ score ($r = .60$, $p < .01$). Rector and Cohn (1992) assessed patient outcomes with the MLHFQ in a randomized, double-blind, placebo-controlled trial of pimobendan with 181 participants. The reliability of all three scores (i.e., total, physical and emotional), were, respectively, .93, .89, and .88 at baseline. The inter-item correlation means at baseline were .94, .94, and .90. Rector et al. (1993) conducted a randomized, controlled trial using different medication groups. Reliability of the MLHFQ was indicated by Spearman's correlation coefficient was .87. In a study by Gorkin,

Norvell, Rosen, Charles, Shumaker, and McIntyre (1993) of 318 patients with left ventricular dysfunction quality of life was examined. Internal consistency reliability in that study was .95 when seen in participants with Class I ($n = 135$) using the NYHA classifications and .94 in Class II and III classifications ($n = 123$). Bennett, Pressler, Hays, Firestine, and Huster (1997) conducted a study with 65 patients in an outpatient CHF clinic. Cronbach's alpha reliability coefficients were .92 (total MLHFQ), .91 (Physical subscale), and .79 (Emotional subscale). Bennett, Oldridge, Eckert, Embree, Browning, and Hou (2003) reported a total score or .95 Cronbach's alpha (with physical score being .94 and emotional .89) at baseline with 211 participants. At 26 weeks, with 165 participants, the Cronbach's alpha was .95 (physical score was .91 and emotional score was .86). In another article by Bennett, Oldridge, Eckert, Embree, Browning, and Hou (2002), data from the previous study were used. Construct validity of the MLHFQ was supported by factor analysis with factors accounting for 70% of the observed variance. Convergent validity was supported for the MLHFQ as it was compared to the SF-12 and the Chronic Heart Failure questionnaire (CHQ). Divergent validity of the MLHFQ was supported by analyzing the differences in the questionnaire and scores of the New York Heart Association (NYHA) classifications. The lower the NYHA score, the better the MLHFQ scores: or the reverse was true with higher NYHA scores associated with poorer MLHFQ scores. A summary of reliability and validity of the MLHFQ is in Table 4. A summary linking terms and conceptual and operational definitions to instruments used within this study is provided in Table 5.

Table 4

Reliability and Validity of the MLHFQ

Study	Sample Size	Psychometric Properties
Rector, Francis, & Cohn. (1987)	83 patients	Weighted kappa for reproducibility for both scores = .84 Validity = highly correlated with global health ($r = .80$, $p < 0.01$); correlated with NYHA ($r = .60$, $p < .01$)
Rector and Cohon (1992)	Randomized, double-blind, placebo-controlled trial; 181 participants	Repeated baseline scores = $r = .93$, 0.89 (physical), and $.88$ (emotional) Cronbach's alpha – $.94$, $.94$, and $.90$ ($n = 197$)
Rector et al. (1993)	152 participants	Correlation coefficients between repeated baseline scores = $.87$
Gorkin, Norvell, Rosen, Charles, Shumaker, & McIntyre (1993)	318 patients with left ventricular dysfunction	Internal consistency = $.95$ (Class 1; $n = 135$) and $.94$ (Class II and III; $n = 123$)

Table 4 (Continued)

Reliability and Validity of the MLHFQ

Study	Sample Size	Psychometric Properties
Bennett, Pressler, Hays, Firestine, & Huster (1997)	65 patients with CHF	Cronbach's alpha = .92 (Total score), .91 (Physical), and .79 (Emotional)
Bennett, Oldridge, Eckert, Embree, Browning, & Hou (2003)	211 participants	Cronbach's alpha = .95 (Total); at 26 weeks .95 (Total), .91 (Physical), and .86 (Emotional)
Bennett, Oldridge, Eckert, Embree, Browning, & Hou (2002)	211 participants	Construct validity – factor analysis with 70% observed variance Convergent validity – supported Divergent validity supported

Table 5

Terms, Conceptual and Operational Definitions, and Instruments

Terms	Conceptual Definition	Operational Definition	Instrument
Age	The time, in years, from birth to the present year (Taber's Cyclopedic Medical Dictionary, 2005).	The individual's self-reported age in years.	General Information Form (GIF)
Ethnicity/Race	"of or relating to large groups of people classes according to common racial, national, tribal, religious, linguistic, or cultural origin or background" (Merriam-Webster Online Dictionary, 2006, p. 1).	Answered by the client agreeing to complete the questionnaires. Categories, or items, for response on the general information form (GIF) include: American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Not Hispanic or Latino, Native Hawaiian or Other Pacific Islander, and White.	GIF
Living Status	Whether the individual lives alone, lives with someone. or lives in a residential setting.	The participant will choose one of the following categories: lives alone, lives with someone, or lives in a residential setting.	GIF

Table 5 (Continued)

Terms, Conceptual and Operational Definitions, and Instruments

Terms	Conceptual Definition	Operational Definition	Instrument
Perceived General Health Status	The individual's perception of his or her health status.	The participant will choose one of the following categories: excellent, very good, good, fair, or poor.	GIF
Perceived Symptom Management	The individual's perception of how the symptoms of heart failure are being managed or controlled.	Symptom management will be measured by a Likert-type scale from 1 (symptoms not being managed well at all) to 10 (symptoms being managed extremely well). The higher the score, the better the symptom management.	GIF

Table 5 (Continued 2)

Terms, Conceptual and Operational Definitions, and Instruments

Terms	Conceptual Definition	Operational Definition	Instrument
Number of Comorbidities	The number of different health-related diagnoses the participant has.	The participant will choose from the following categories: heart disease, high blood pressure, lung disease, diabetes, ulcer or stomach disease, kidney disease, liver disease, anemia or other blood disease, cancer, depression, osteoarthritis, degenerative arthritis, back pain, rheumatoid arthritis, thyroid disease, obesity, autoimmune disease, and other.	GIF

Table 5 (Continued 3)

Terms, Conceptual and Operational Definitions, and Instruments

Terms	Conceptual Definition	Operational Definition	Instrument
Health-related quality of life	“the relationship between two concepts, health or disease (in this case heart failure) and QOL” (A. Brown, personal communication, July 12, 2006).	The MLHFQ is a QOL instrument specifically for heart failure patients. This questionnaire consists of 21 questions. Persons may respond to each question using a 6-point Likert-type scale where 0 equals “no”, 1 equals “very little”, and 5 equals “very much”. The lower the score, the better the QOL and the higher score represents a poorer QOL. Reliability for the MLHFQ is .95 - .87 (Rector, 2005).	MLHFQ

Table 5 (Continued 4)

Terms, Conceptual and Operational Definitions, and Instruments

Terms	Conceptual Definition	Operational Definition	Instrument
Health Status	“an overall evaluation of an individual's degree of wellness or illness with a number of indicators, including quality of life and functionality” (Ware, Kosinski, & Dewey, 2002).	The SF-36v2 is a 36-item instrument used to measure physical and mental health status. The survey yields an 8 scale profile of scores. Physical and mental health summary measures are also provided. Items and scales are scored so that a higher score indicates a better health status. Reliability of the SF-36v2 scales range from .84 to .95 (Ware, Kosinski, & Dewey, 2002).	SF-36v2

Data Collection

This study used a cross-sectional exploratory design. The sample included men and women with a diagnosis of CHF who were attending a CHF clinic for treatment. Individuals 18 years and older diagnosed with CHF were asked to participate and complete three questionnaires while in the clinic setting. The questionnaires were numbered, with an assigned number given to each participant. Numbers were used only for organization of the data. They did not personally identify the participant.

Treatment of Data

Descriptive statistics, as appropriate to the level of data, were used to describe the sample; these included such statistics as measures of central tendency, frequencies, and percentages. Frequencies and percentages were used to report gender, race, comorbidities, and living status; measures of central tendency (e.g., means and standard deviations) were appropriate for remaining data describing participants. Levels of measurement included nominal (e.g., gender, ethnicity/race, and living status, and specific comorbidities), ordinal (e.g., test score totals), and interval or ratio (e.g., number of comorbidities). A decision was made to treat the test scores (i.e., MANOVA, independent *t* tests, chi-square, hierarchical multiple regression analysis, and Kappa statistic) as interval data since they were arranged in almost equal intervals (Field, 2005). Initially, exploratory data analysis was used for reviewing these data to assure that assumptions were met for running the statistical analyses and to look for any underlying patterns.

Research Question 1

Multiple analysis of variance (MANOVA) was the statistical test used to examine the research question: Are there differences in self-reported health status and HRQOL of men and women with a diagnosis of CHF? MANOVA was used to test multiple dependent variables, examining the significance of differences in group means (Polit & Beck, 2008). The independent variable was gender and the dependent variables were health status and HRQOL. The null hypothesis was: There is no significant difference in the health status and HRQOL of women and men with a CHF diagnosis.

Research Question 2

Independent t tests and chi-square test of independence tested the second research question: Are there gender differences in specified variables (i.e., age, race/ethnicity, living status, number of comorbidities, perceived general health status, and perceived symptom management) of those with a diagnosis of CHF? Independent t tests were used to statistically test the difference in means of males and females with CHF on age, number of comorbidities, perceived general health status, and perceived symptom management (Portney and Watkins, 2009). Chi-square test of independence was used to test the independence between two variables (i.e., race/ethnicity and living status) measured on a nominal scale (Portney & Watkins, 2009).

Research Questions 3 and 4

Hierarchical multiple regression analysis was used to test Questions 3 and 4. Research Question 3 asked “Are gender, age, race/ethnicity, number of comorbidities, living status, perceived general health status, perceived physical health status, perceived mental health status, and perceived symptom management significant predictors of HRQOL?” Research Question 4 asked “Do symptom status (i.e., perceived symptom management), functional status (i.e., living status, perceived physical health status, and perceived mental health status), and general health perceptions (i.e., perceived general health status) serve as mediating variables between the exogenous variables (i.e., gender, age, race/ethnicity, and comorbidities) and overall quality of life?” Hierarchical multiple regression analysis is primarily used to create an equation to help in understanding what variables are important in the prediction of some dependent variables (Mertler &

Vannatta, 2002). Prior to data analysis, the theoretical and statistical assumptions were tested. Residual plots were used to check assumptions of linearity and normality; any outlying values were examined and a decision was made about their inclusion in the analysis. Hierarchical multiple regression was conducted to determine any predictors of HRQOL.

Research Question 5

A kappa coefficient was used to analyze Research Question 5: Is there agreement of the New York Heart Association's (NYHA) Functional Class ratings made by the participant and his/her health care provider? Kappa statistic was used to measure chance-corrected measure of agreement (Portney & Watkins, 2009).

Significance of the Study

There are long-term health-related effects in individuals diagnosed with CHF. This research study will increase the understanding of these and which are significant predictors of quality of life. Findings are expected to inform nursing practice so that interventions may be planned to improve the quality of life of individuals with CHF. Educating individuals with CHF while monitoring their health status, helping with goal setting, and establishing avenues of support for them and their families should enable them to make decisions that could add to a better HRQOL.

Summary

In summary, this chapter has presented the cross-sectional exploratory design for this study. Specific issues such as participant selection, setting, sample, protection of human subjects, instrument description including validity and reliability, data collection

techniques and treatment of data have been discussed. Five research questions guided the data analysis, and the statistical measures used in relation to each were discussed. Rationale for each step has been provided and selected techniques for statistical analysis substantiated.

CHAPTER IV

ANALYSIS OF DATA

The major study question addressed was “Are there differences in self-reported health status and health-related quality of life (HRQOL) of men and women with a diagnosis of congestive heart failure (CHF)?” This chapter presents the study findings that addressed the following five specific research questions using an exploratory cross-sectional study design:

1. Are there differences in self-reported health status and HRQOL of men and women with a diagnosis of CHF?
2. Are there differences in age, race/ethnicity, living status, number of comorbidities, perceived general health status, and perceived symptom management of men and women with a diagnosis of CHF?
3. Are gender, age, race/ethnicity, number of comorbidities, living status, perceived general health status, perceived physical health status, perceived mental health and perceived symptom management significant predictors of HRQOL?
4. Do symptom status (i.e., perceived symptom management), functional status (i.e., perceived physical health status and perceived mental health status), and general health perceptions (i.e., perceived general health status) serve as

mediating variables between the exogenous variables (i.e., gender, age, race/ethnicity, and comorbidities) and HRQOL.?

5. Is there agreement of the New York Heart Association's (NYHA) Functional Class ratings made by the participant and his/her health care provider?

Description of the Sample

The study sample met the following criteria for participation: (a) a diagnosis of CHF, (b) 18 years of age or greater, and (c) physically and mentally able to complete the study questionnaires. The majority of participants ($n = 108$) were recruited from a cardiology clinic in Houston, Texas, and the remaining participants ($n = 5$) were from a cardiology clinic in Dallas, Texas. A non-probability, convenience sample of 113 clients volunteers to participate in this study that extended over a 4-month period from May 2007 to August 2007.

Sample Demographics and General Health Information

Sample demographics and general health information are displayed in Table 6. Participants ranged in age from 40 to 95 years with a mean age of 68 ($SD = 11.9$) years. Sixty-seven percent were male and 33% were female. Seventy-seven percent of participants were Caucasian, 11% were black or African-American, and 12% were listed as "other". Eighty-four percent lived with someone and 16% lived alone. The mean household income was estimated at \$48,178.83 ($SD = 15,177.62$) and the mean house value was estimated at \$84,623.64 ($SD = 32,612.16$).

Sixty-one percent of participants perceived their general health status to be good or better when rated on a scale from *poor* to *excellent*. Using a Likert-type scale,

participants rated their CHF symptom management with scores ranging from 1 (*not well at all*) to 10 (*extremely well*). Their average CHF symptom management rating score was 7.2 on a scale of 0 to 10. Participants were asked to identify all of their diagnosed diseases. Sixty percent had at least 3 comorbidities. Other than CHF, the most frequent major health issues of these participants were as follows: heart disease (79%), high blood pressure (66%), back pain (28%), diabetes (27%), and degenerative arthritis (22%). Sixteen percent indicated they were currently taking antidepressant medication. Cost of medications (22%) and cost of medical care (30%) were noted as contributing to financial stress affecting quality of life.

Demographics of this sample varied among gender and ethnic groups. The sample included, in order of number of participants, Caucasian men (53%), Caucasian women (24 %), African-American men (7%), and African-American women (4%). Women (21.6%) were more likely to live alone than were males (13.2%).

Women had a higher mean age (71.19, $SD = 12.09$) than did men (67.05, $SD = 11.58$). Women's ages ranged from 43 to 95 years of age, with men ranging in age from 40 to 93 years. Women had a higher perceived general health status mean, 2.97 ($SD = .928$) than did men, 2.75 ($SD = .940$). However, men had a higher perceived CHF symptom management score mean (7.34, $SD = 2.16$) than did women (6.92, $SD = 2.37$).

Men had a higher house hold income (\$48,746.49, $SD = \$16,032.18$) and a higher house value (\$87,067.57, $SD = \$35,958.92$) than did women (\$47,011.97, $SD = \$13,387.80$) (\$79,600.00, $SD = 24,014.60$). Cost of medications and cost of medical care were noted as contributing to financial stress affecting quality of life. Twenty-seven

percent of women and 19.7% of men noted that their cost of medications impaired their QOL. Men had a slightly higher percentage (30.3%) than women (27%) in their perception that the cost of their medical care impaired their QOL.

Women had a higher percentage in the following comorbidity categories: heart disease (83.8%), blood pressure (67.6%) , lung disease (13.5%), ulcer or stomach disease (16.2%), kidney disease (13.5%), anemia and other blood disease (8.1%), cancer (8.1%), osteoarthritis and/or degenerative arthritis (32.4%), back pain (35.1%) , rheumatoid arthritis (16.2%), thyroid (16.2%), and sleep apnea (13.5 %). Men experienced a higher rate of diabetes mellitus (30.3%), liver disease (2.6%), depression (14.5%), and obesity (19.7%). While men had a higher incidence of depression, women (21.6%) noted taking more medication for depression than men (13.2%).

An overwhelming majority of participants (85, 75.2%) did not know their ejection fraction (EF) (see Table 1). From 50% to 100% of participants did not know their EF. By percentage, those who showed the greatest knowledge deficit were African American men (50%) and men of “other” descent (100%).

Hospitalizations

Hospitalizations and the reason for hospitalizations were of interest in learning more about the sample and their health status (see Tables 6 and 7). Participants were asked “When were you last admitted to the hospital?” Also, “What symptoms prompted you to go to the hospital?” Thirty-four percent of the participants reported having been admitted to the hospital within the past year. Only 5% ($n = 6$) participants reported never having been hospitalized. Overall, the stated reasons for hospital admission were as

follows: shortness of breath, 33% ($n = 37$), chest pain, 26% ($n = 29$); fatigue (tiredness), 19% ($n = 21$); swelling, 12% ($n = 14$); defibrillator responding, 1% ($n = 1$); and other reasons, 49% ($n = 55$).

Women were admitted more often than men a year ago or more (70.3%) or less than 3 months ago (8.1%). Men were more often admitted between 3 and 6 months (11.8%) or 6 months to 1 year (21.1%) from the time of questioning. Approximately 5% of women and men had never been admitted to a hospital.

Women had a higher percentage of swelling (21.6%), shortness of breath (35.1%), and “other” symptoms (56.8%) prompting them to go to the hospital. Men had a higher percentage of chest pain (27.6%) and defibrillator responding (1.3%) as to the symptoms that prompted them. Fatigue was essentially the same, 18%, for both groups.

Table 6

Demographics

	Age	Co-Habitate	Household Income	Estimated Home Value
All Participants (<i>N</i> = 113)	<i>M</i> (<i>SD</i>): 68.41(11.86)	Yes: 84.1% (<i>n</i> = 95) No: 15.9 % (<i>n</i> = 18)	<i>M</i> (<i>SD</i>) = 48,178.83 (15,177.62)	<i>M</i> (<i>SD</i>): 84,623.64 (32,612.16)
All Women 33% (<i>n</i> = 37)	<i>M</i> (<i>SD</i>): 71.19 (12.09)	Yes: 78.4 % (<i>n</i> = 29) No: 21.6 % (<i>n</i> = 8)	<i>M</i> (<i>SD</i>): 47,011.97 (13,387.80)	<i>M</i> (<i>SD</i>): 79,600 (24,014.60)
All Men 67% (<i>n</i> = 76)	<i>M</i> (<i>SD</i>): 67.05 (11.58)	Yes: 86.8 % (<i>n</i> = 66) No: 13.2 % (<i>n</i> = 10)	<i>M</i> (<i>SD</i>): 48,746.49 (16,032.18)	<i>M</i> (<i>SD</i>): 87,067.57 (35,958.92)
African American Women Only 4% (<i>n</i> = 4)	<i>M</i> (<i>SD</i>): 60.50 (19.50)	Yes: 50 % (<i>n</i> = 2) No: 50 % (<i>n</i> = 2)	<i>M</i> (<i>SD</i>): 31,371.50 (6,813.46)	<i>M</i> (<i>SD</i>): 58,950.00(17,845.73)
Caucasian Women Only 24% (<i>n</i> = 27)	<i>M</i> (<i>SD</i>): 72.33 (10.83)	Yes: 77.8 % (<i>n</i> = 21) No: 22.2 % (<i>n</i> = 6)	<i>M</i> (<i>SD</i>): 50,565.38 (11,930.786)	<i>M</i> (<i>SD</i>): 85,288.46 (22,725.85)
Women of “Other” Descent 5% (<i>n</i> = 6)	<i>M</i> (<i>SD</i>): 73.17 (10.55)	Yes: 100 % (<i>n</i> = 6) No: 0 % (<i>n</i> = 0)	<i>M</i> (<i>SD</i>): 42,040.83 (14,968.20)	<i>M</i> (<i>SD</i>): 68,716.67 (24,737.94)
Caucasian Men Only 53% (<i>n</i> = 60)	<i>M</i> (<i>SD</i>): 68.50 (11.61)	Yes: 83.3 % (<i>n</i> = 50) No: 16.7 % (<i>n</i> = 10)	<i>M</i> (<i>SD</i>): 50,406.64 (14,230.89)	<i>M</i> (<i>SD</i>): 90,163.79 (34,977.10)
African American Men Only 7% (<i>n</i> = 8)	<i>M</i> (<i>SD</i>): 58.13 (7.10)	Yes: 100 % (<i>n</i> = 8) No: 0 % (<i>n</i> = 0)	<i>M</i> (<i>SD</i>): 46,824.63 (25,927.46)	<i>M</i> (<i>SD</i>): 86,575.00 (50,124.47)
Men of “Other” Descent 7% (<i>n</i> = 8)	<i>M</i> (<i>SD</i>): 65.13 (11.77)	Yes: 100 % (<i>n</i> = 8) No: 0 % (<i>n</i> = 0)	<i>M</i> (<i>SD</i>): 38,632.25 (14,669.17)	<i>M</i> (<i>SD</i>): 65,112.50 (19,483.07)

Table 6 (Continued)

Demographics

	General Health Status “Excellent”	General Health Status “Very Good”	General Health Status “Good”	General Health Status “Fair”	General Health Status “Poor”
All Participants (<i>N</i> = 113)	2.7% (<i>n</i> = 3)	22.1% (<i>n</i> = 25)	36.3% (<i>n</i> = 41)	32.7% (<i>n</i> = 37)	6.2% (<i>n</i> = 7)
All Women 33% (<i>n</i> = 37)	2.7% (<i>n</i> = 1)	27% (<i>n</i> = 10)	40.5% (<i>n</i> = 15)	24.3% (<i>n</i> = 9)	5.4% (<i>n</i> = 2)
All Men 67% (<i>n</i> = 76)	2.6% (<i>n</i> = 2)	19.7% (<i>n</i> = 15)	34.2% (<i>n</i> = 26)	36.8% (<i>n</i> = 28)	6.6% (<i>n</i> = 5)
African American Women Only 4% (<i>n</i> = 4)	0% (<i>n</i> = 0)	25% (<i>n</i> = 1)	50% (<i>n</i> = 2)	25% (<i>n</i> = 1)	0% (<i>n</i> = 0)
Caucasian Women Only 24% (<i>n</i> = 27)	3.7% (<i>n</i> = 1)	25.9% (<i>n</i> = 7)	40.7% (<i>n</i> = 11)	25.9% (<i>n</i> = 7)	3.7% (<i>n</i> = 1)
Women of “Other” Descent 5% (<i>n</i> = 6)	0% (<i>n</i> = 0)	33.3% (<i>n</i> = 2)	33.3% (<i>n</i> = 2)	16.7% (<i>n</i> = 1)	16.7% (<i>n</i> = 1)
Caucasian Men Only 53% (<i>n</i> = 60)	1.7% (<i>n</i> = 1)	20% (<i>n</i> = 12)	38.3% (<i>n</i> = 23)	31.7% (<i>n</i> = 19)	8.3% (<i>n</i> = 5)
African American Men Only 7% (<i>n</i> = 8)	0% (<i>n</i> = 0)	12.5% (<i>n</i> = 1)	12.5% (<i>n</i> = 1)	75% (<i>n</i> = 6)	0% (<i>n</i> = 0)
Men of “Other” Descent 7% (<i>n</i> = 8)	12.5% (<i>n</i> = 1)	25% (<i>n</i> = 2)	25% (<i>n</i> = 2)	37.5% (<i>n</i> = 3)	0% (<i>n</i> = 0)

Table 6 (Continued 2)

Demographics

	CHF Symptom Management Score	Taking medication for Depression	Cost of medications impairs QOL	Cost of medical care impairs QOL
All Participants (<i>N</i> = 113)	<i>M</i> (<i>SD</i>) = 7.20 (2.23) Range: 1-10	15.9% (<i>n</i> = 18)	22.1% (<i>n</i> = 25)	29.2% (<i>n</i> = 33)
All Women 33% (<i>n</i> = 37)	<i>M</i> (<i>SD</i>) = 6.92 (2.37) Range: 1-10	21.6% (<i>n</i> = 8)	27% (<i>n</i> = 10)	27% (<i>n</i> = 10)
All Men 67% (<i>n</i> = 76)	<i>M</i> (<i>SD</i>) = 7.34 (2.16) Range: 1-10	13.2% (<i>n</i> = 10)	19.7% (<i>n</i> = 15)	30.3% (<i>n</i> = 23)
African American Women Only 4% (<i>n</i> = 4)	<i>M</i> (<i>SD</i>) = 6.50 (2.38) Range: 3-8	25% (<i>n</i> = 1)	25% (<i>n</i> = 1)	25% (<i>n</i> = 1)
Caucasian Women Only 24% (<i>n</i> = 27)	<i>M</i> (<i>SD</i>) = 6.93 (2.27) Range: 1-10	22.2% (<i>n</i> = 6)	18.5% (<i>n</i> = 5)	18.5% (<i>n</i> = 5)
Women of "Other" Descent 5% (<i>n</i> = 6)	<i>M</i> (<i>SD</i>) = 7.17 (3.19) Range: 1-10	16.7% (<i>n</i> = 1)	66.7% (<i>n</i> = 4)	66.7% (<i>n</i> = 4)
Caucasian Men Only 53% (<i>n</i> = 60)	<i>M</i> (<i>SD</i>) = 7.27 (2.21) Range: 1-10	16.7% (<i>n</i> = 10)	20% (<i>n</i> = 12)	30% (<i>n</i> = 18)
African American Men Only 7% (<i>n</i> = 8)	<i>M</i> (<i>SD</i>) = 7.25 (1.58) Range: 5-10	0% (<i>n</i> = 0)	25% (<i>n</i> = 2)	37.5% (<i>n</i> = 3)
Men of "Other" Descent 7% (<i>n</i> = 8)	<i>M</i> (<i>SD</i>) = 8.00 (2.39) Range: 4-10	0% (<i>n</i> = 0)	12.5% (<i>n</i> = 1)	25% (<i>n</i> = 2)

Table 6 (Continued 3)

Demographics

	Hospitalized < 3 months ago	Hospitalized 3 to 6 months ago	Hospitalized 6 months to < 1 year ago	Hospitalized >1 year ago	Never Hospitalized
All Participants (N= 113)	6.2% (n = 7)	8.8% (n = 10)	18.6% (n = 21)	61.1% (n = 69)	5.3% (n = 6)
All Women 33% (n = 37)	8.1% (n = 3)	2.7% (n = 1)	13.5% (n = 5)	70.3% (n = 26)	5.4% (n = 2)
All Men 67% (n = 76)	5.3% (n = 4)	11.8% (n = 9)	21.1% (n = 16)	56.6% (n = 43)	5.3% (n = 4)
African American Women Only 4% (n = 4)	0% (n = 0)	0% (n = 0)	0% (n = 0)	100% (n = 4)	0% (n = 0)
Caucasian Women Only 24% (n = 27)	7.4% (n = 2)	3.7% (n = 1)	14.8% (n = 4)	66.7% (n = 18)	7.4% (n = 2)
Women of "Other" Descent 5% (n = 6)	16.7% (n = 1)	0% (n = 0)	16.7% (n = 1)	66.7% (n = 4)	0% (n = 0)
Caucasian Men Only 53% (n = 60)	6.7% (n = 4)	13.3% (n = 8)	21.7% (n = 13)	53.3% (n = 32)	5% (n = 3)
African American Men Only 7% (n = 8)	0% (n = 0)	12.5% (n = 1)	12.5% (n = 1)	75% (n = 6)	0% (n = 0)
Men of "Other" Descent 7% (n = 8)	0% (n = 0)	0% (n = 0)	25% (n = 2)	62.5% (n = 5)	12.5% (n = 1)

Table 6 (Continued 4)

Demographics

	Comorbidity Heart Disease	Comorbidity High Blood Pressure	Comorbidity Lung Disease	Comorbidity Diabetes	Comorbidity Ulcer or Stomach Disease
All Participants (<i>N</i> = 113)	78.8% (<i>n</i> = 89)	66.4% (<i>n</i> = 75)	11.5% (<i>n</i> = 13)	27.4% (<i>n</i> = 31)	8% (<i>n</i> = 9)
All Women 33% (<i>n</i> = 37)	83.8% (<i>n</i> = 31)	67.6% (<i>n</i> = 25)	13.5% (<i>n</i> = 5)	21.6% (<i>n</i> = 8)	16.2% (<i>n</i> = 6)
All Men 67% (<i>n</i> = 76)	76.3% (<i>n</i> = 58)	65.8% (<i>n</i> = 50)	10.5% (<i>n</i> = 8)	30.3% (<i>n</i> = 23)	3.9% (<i>n</i> = 3)
African American Women Only 4% (<i>n</i> = 4)	75% (<i>n</i> = 3)	75% (<i>n</i> = 3)	0% (<i>n</i> = 0)	50% (<i>n</i> = 2)	0% (<i>n</i> = 0)
Caucasian Women Only 24% (<i>n</i> = 27)	92.6% (<i>n</i> = 25)	63% (<i>n</i> = 17)	18.5% (<i>n</i> = 5)	14.8% (<i>n</i> = 4)	14.8% (<i>n</i> = 4)
Women of “Other” Descent 5% (<i>n</i> = 6)	50% (<i>n</i> = 3)	83.3% (<i>n</i> = 5)	0% (<i>n</i> = 0)	33.3% (<i>n</i> = 2)	33.3% (<i>n</i> = 2)
Caucasian Men Only 53% (<i>n</i> = 60)	73.3% (<i>n</i> = 44)	66.7% (<i>n</i> = 40)	10% (<i>n</i> = 6)	31.7% (<i>n</i> = 19)	5% (<i>n</i> = 3)
African American Men Only 7% (<i>n</i> = 8)	100% (<i>n</i> = 8)	75% (<i>n</i> = 6)	12.5% (<i>n</i> = 1)	12.5% (<i>n</i> = 1)	0% (<i>n</i> = 0)
Men of “Other” Descent 7% (<i>n</i> = 8)	75% (<i>n</i> = 6)	50% (<i>n</i> = 4)	12.5% (<i>n</i> = 1)	37.5% (<i>n</i> = 3)	0% (<i>n</i> = 0)

Table 6 (Continued 5)

Demographics

	Comorbidity Kidney Disease	Comorbidity Liver Disease	Comorbidity Anemia or other Blood Disease	Comorbidity Cancer	Comorbidity Depression
All Participants (<i>N</i> = 113)	9.7% (<i>n</i> = 11)	1.8% (<i>n</i> = 2)	2.7% (<i>n</i> = 3)	7.1% (<i>n</i> = 8)	14.2% (<i>n</i> = 16)
All Women 33% (<i>n</i> = 37)	13.5% (<i>n</i> = 5)	0% (<i>n</i> = 0)	8.1% (<i>n</i> = 3)	8.1% (<i>n</i> = 3)	13.5% (<i>n</i> = 5)
All Men 67% (<i>n</i> = 76)	7.9% (<i>n</i> = 6)	2.6% (<i>n</i> = 2)	0% (<i>n</i> = 0)	6.6% (<i>n</i> = 5)	14.5% (<i>n</i> = 11)
African American Women Only 4% (<i>n</i> = 4)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	25% (<i>n</i> = 1)	0% (<i>n</i> = 0)	25% (<i>n</i> = 1)
Caucasian Women Only 24% (<i>n</i> = 27)	11.1% (<i>n</i> = 3)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	11.1% (<i>n</i> = 3)	11.1% (<i>n</i> = 3)
Women of “Other” Descent 5% (<i>n</i> = 6)	33.3% (<i>n</i> = 2)	0% (<i>n</i> = 0)	33.3% (<i>n</i> = 2)	0% (<i>n</i> = 0)	16.7% (<i>n</i> = 1)
Caucasian Men Only 53% (<i>n</i> = 60)	8.3% (<i>n</i> = 5)	3.3% (<i>n</i> = 2)	0% (<i>n</i> = 0)	6.7% (<i>n</i> = 4)	16.7% (<i>n</i> = 10)
African American Men Only 7% (<i>n</i> = 8)	12.5% (<i>n</i> = 1)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	12.5% (<i>n</i> = 1)	12.5% (<i>n</i> = 1)
Men of “Other” Descent 7% (<i>n</i> = 8)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)

Table 6 (Continued 6)

Demographics

	Comorbidity Osteoarthritis	Comorbidity Back Pain	Comorbidity Rheumatoid Arthritis	Comorbidity Thyroid Disease	Comorbidity Obesity
All Participants (<i>N</i> = 113)	22.1% (<i>n</i> = 25)	28.3% (<i>n</i> = 32)	12.4% (<i>n</i> = 14)	9.7% (<i>n</i> = 11)	18.6% (<i>n</i> = 21)
All Women 33% (<i>n</i> = 37)	32.4% (<i>n</i> = 12)	35.1% (<i>n</i> = 13)	16.2% (<i>n</i> = 6)	16.2% (<i>n</i> = 6)	16.2% (<i>n</i> = 6)
All Men 67% (<i>n</i> = 76)	17.1% (<i>n</i> = 13)	25% (<i>n</i> = 19)	10.5% (<i>n</i> = 8)	6.6% (<i>n</i> = 5)	19.7% (<i>n</i> = 15)
African American Women Only 4% (<i>n</i> = 4)	0% (<i>n</i> = 0)	25% (<i>n</i> = 1)	25% (<i>n</i> = 1)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)
Caucasian Women Only 24% (<i>n</i> = 27)	33.3% (<i>n</i> = 9)	40.7% (<i>n</i> = 11)	11.1% (<i>n</i> = 3)	18.5% (<i>n</i> = 5)	14.8% (<i>n</i> = 4)
Women of "Other" Descent 5% (<i>n</i> = 6)	50% (<i>n</i> = 3)	16.7% (<i>n</i> = 1)	33.3% (<i>n</i> = 2)	16.7% (<i>n</i> = 1)	33.3% (<i>n</i> = 2)
Caucasian Men Only 53% (<i>n</i> = 60)	20% (<i>n</i> = 12)	25% (<i>n</i> = 15)	6.7% (<i>n</i> = 4)	8.3% (<i>n</i> = 5)	23.3% (<i>n</i> = 14)
African American Men Only 7% (<i>n</i> = 8)	0% (<i>n</i> = 0)	25% (<i>n</i> = 2)	25% (<i>n</i> = 2)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)
Men of "Other" Descent 7% (<i>n</i> = 8)	12.5% (<i>n</i> = 1)	25% (<i>n</i> = 2)	25% (<i>n</i> = 2)	0% (<i>n</i> = 0)	12.5% (<i>n</i> = 1)

Table 6 (Continued 7)

Demographics

	Comorbidity Autoimmune Disease	Comorbidity Sleep Apnea	Comorbidity “Other”	Total Number of Comorbidities	Participants with One Comorbidity	Participants with Two Comorbidities
All Participants (<i>N</i> = 113)	0% (<i>n</i> = 0)	13.3% (<i>n</i> = 15)	3.5% (<i>n</i> = 4)	<i>M</i> (<i>SD</i>) = 3.35 (1.86)	14.2% (<i>n</i> = 16)	25.7% (<i>n</i> = 29)
All Women 33% (<i>n</i> = 37)	0% (<i>n</i> = 0)	13.5% (<i>n</i> = 5)	0% (<i>n</i> = 0)	<i>M</i> (<i>SD</i>) = 3.76 (1.86)	8.1% (<i>n</i> = 3)	27% (<i>n</i> = 10)
All Men 67% (<i>n</i> = 76)	0% (<i>n</i> = 0)	13.2% (<i>n</i> = 10)	5.3% (<i>n</i> = 4)	<i>M</i> (<i>SD</i>) = 3.16 (1.83)	17.1% (<i>n</i> = 13)	25% (<i>n</i> = 19)
African American Women Only 4% (<i>n</i> = 4)	0% (<i>n</i> = 0)	25% (<i>n</i> = 1)	0% (<i>n</i> = 0)	<i>M</i> (<i>SD</i>) = 3.25 (2.06)	25% (<i>n</i> = 1)	25% (<i>n</i> = 1)
Caucasian Women Only 24% (<i>n</i> = 27)	0% (<i>n</i> = 0)	7.4% (<i>n</i> = 2)	0% (<i>n</i> = 0)	<i>M</i> (<i>SD</i>) = 3.63 (1.86)	7.4% (<i>n</i> = 2)	33.3% (<i>n</i> = 9)
Women of “Other” Descent 5% (<i>n</i> = 6)	0% (<i>n</i> = 0)	33.3% (<i>n</i> = 2)	0% (<i>n</i> = 0)	<i>M</i> (<i>SD</i>) = 4.67 (1.75)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)
Caucasian Men Only 53% (<i>n</i> = 60)	0% (<i>n</i> = 0)	13.3% (<i>n</i> = 8)	5% (<i>n</i> = 3)	<i>M</i> (<i>SD</i>) = 3.23 (1.96)	18.3% (<i>n</i> = 11)	23.3% (<i>n</i> = 14)
African American Men Only 7% (<i>n</i> = 8)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	12.5% (<i>n</i> = 1)	<i>M</i> (<i>SD</i>) = 3 (1.07)	0% (<i>n</i> = 0)	37.5% (<i>n</i> = 3)
Men of “Other” Descent 7% (<i>n</i> = 8)	0% (<i>n</i> = 0)	25% (<i>n</i> = 2)	0% (<i>n</i> = 0)	<i>M</i> (<i>SD</i>) = 2.75 (1.49)	25% (<i>n</i> = 2)	25% (<i>n</i> = 2)

Table 6 (Continued 8)

Demographics

	Participants with Three Comorbidities	Participants with Four Comorbidities	Participants with Five Comorbidities	Participants with Six Comorbidities	Participants with Seven Comorbidities
All Participants (<i>N</i> = 113)	18.6% (<i>n</i> = 21)	17.7% (<i>n</i> = 20)	13.3% (<i>n</i> = 15)	2.7% (<i>n</i> = 3)	3.5% (<i>n</i> = 4)
All Women 33% (<i>n</i> = 37)	10.8% (<i>n</i> = 4)	16.2% (<i>n</i> = 6)	24.3% (<i>n</i> = 9)	2.7% (<i>n</i> = 1)	8.1% (<i>n</i> = 3)
All Men 67% (<i>n</i> = 76)	22.4% (<i>n</i> = 17)	18.4% (<i>n</i> = 14)	7.9% (<i>n</i> = 6)	2.6% (<i>n</i> = 2)	1.3% (<i>n</i> = 1)
African American Women Only 4% (<i>n</i> = 4)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	50% (<i>n</i> = 2)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)
Caucasian Women Only 24% (<i>n</i> = 27)	11.1% (<i>n</i> = 3)	11.1% (<i>n</i> = 3)	22.2% (<i>n</i> = 6)	3.7% (<i>n</i> = 1)	11.1% (<i>n</i> = 3)
Women of "Other" Descent 5% (<i>n</i> = 6)	16.7% (<i>n</i> = 1)	50% (<i>n</i> = 3)	16.7% (<i>n</i> = 1)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)
Caucasian Men Only 53% (<i>n</i> = 60)	21.7% (<i>n</i> = 13)	18.3% (<i>n</i> = 11)	6.7% (<i>n</i> = 4)	3.3% (<i>n</i> = 2)	1.7% (<i>n</i> = 1)
African American Men Only 7% (<i>n</i> = 8)	37.5% (<i>n</i> = 3)	12.5% (<i>n</i> = 1)	12.5% (<i>n</i> = 1)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)
Men of "Other" Descent 7% (<i>n</i> = 8)	12.5% (<i>n</i> = 1)	25% (<i>n</i> = 2)	12.5% (<i>n</i> = 1)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)

Table 6 (Continued 9)

Demographics

	Participants with Eight Comorbidities	Participants with Nine Comorbidities	Participants with Ejection Fraction >40%	Participants with Ejection Fraction Equal or <40%	Participants not knowing their Ejection Fraction
All Participants (<i>N</i> = 113)	3.5% (<i>n</i> = 4)	.9% (<i>n</i> = 1)	14.2% (<i>n</i> = 16)	10.6% (<i>n</i> = 12)	75.2% (<i>n</i> = 85)
All Women 33% (<i>n</i> = 37)	2.7% (<i>n</i> = 1)	0% (<i>n</i> = 0)	8.1% (<i>n</i> = 3)	10.8% (<i>n</i> = 4)	81.1% (<i>n</i> = 30)
All Men 67% (<i>n</i> = 76)	3.9% (<i>n</i> = 3)	1.3% (<i>n</i> = 1)	17.1% (<i>n</i> = 13)	10.5% (<i>n</i> = 8)	72.4% (<i>n</i> = 55)
African American Women Only 4% (<i>n</i> = 4)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	25% (<i>n</i> = 1)	75% (<i>n</i> = 3)
Caucasian Women Only 24% (<i>n</i> = 27)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	7.4% (<i>n</i> = 2)	11.1% (<i>n</i> = 3)	81.5% (<i>n</i> = 22)
Women of "Other" Descent 5% (<i>n</i> = 6)	16.7% (<i>n</i> = 1)	0% (<i>n</i> = 0)	16.7% (<i>n</i> = 1)	0% (<i>n</i> = 0)	83.3% (<i>n</i> = 5)
Caucasian Men Only 53% (<i>n</i> = 60)	5% (<i>n</i> = 3)	1.7% (<i>n</i> = 1)	20% (<i>n</i> = 12)	8.3% (<i>n</i> = 5)	71.7% (<i>n</i> = 43)
African American Men Only 7% (<i>n</i> = 8)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	12.5% (<i>n</i> = 1)	37.5% (<i>n</i> = 3)	50% (<i>n</i> = 4)
Men of "Other" Descent 7% (<i>n</i> = 8)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	0% (<i>n</i> = 0)	100% (<i>n</i> = 8)

Table 7

*Symptom That Prompted You
to Go to Hospital*

	Swelling	Shortness of Breath	Fatigue (Tiredness)	Defibrillator Responded	Chest Pain	Other
All Participants (N= 113)	12.4% (n = 14)	32.7% (n = 37)	18.6% (n = 21)	.9% (n = 1)	25.7% (n = 29)	48.7% (n = 55)
All Women 33% (n = 37)	21.6% (n = 8)	35.1% (n = 13)	18.9% (n = 7)	0% (n = 0)	21.6% (n = 8)	56.8% (n = 21)
All Men 67% (n = 76)	7.9% (n = 6)	31.6% (n = 24)	18.4% (n = 14)	1.3% (n = 1)	27.6% (n = 21)	44.7% (n = 34)
African American Women Only 4% (n = 4)	25% (n = 1)	75% (n = 3)	0% (n = 0)	0% (n = 0)	50% (n = 2)	25% (n = 1)
Caucasian Women Only 24% (n = 27)	18.5% (n = 5)	29.6% (n = 8)	18.5% (n = 5)	0% (n = 0)	22.2% (n = 6)	63% (n = 17)
Women of "Other" Descent 5% (n = 6)	33.3% (n = 2)	33.3% (n = 2)	33.3% (n = 2)	0% (n = 0)	0% (n = 0)	50% (n = 3)
Caucasian Men Only 53% (n = 60)	5% (n = 3)	28.3% (n = 17)	20% (n = 12)	1.7% (n = 1)	23.3% (n = 14)	50% (n = 30)
African American Men Only 7% (n = 8)	37.5% (n = 3)	50% (n = 4)	25% (n = 2)	0% (n = 0)	25% (n = 2)	37.5% (n = 3)
Men of "Other" Descent 7% (n = 8)	0% (n = 0)	37.5% (n = 3)	0% (n = 0)	0% (n = 0)	62.5% (n = 5)	12.5% (n = 1)

Ejection fraction is the amount of blood that is ejected from each ventricle contraction and is the index of the left ventricular function. The normal percentage is 65% (Mosby's Medical, Nursing, & Allied Health Dictionary, 1994). The New York Heart Association's (NYHA) Functional Classification is a classification which allows individuals to categorize their functional status while living with heart failure. Typically, as the heart begins to decline in function, the individual will start declining in functional status. Health care providers recorded each participant's EF percent (Table 8). The overall mean EF% was 45.82 ($SD = 14.53$). Of those scores, African American women had the highest mean EF% (54.25, $SD = 21.45$), while African American men had the lowest mean percentage (38, $SD = 13.95$).

The NYHA was recorded by each participant and the participant's health care provider (Table 8). Participants' response ratings were as follows: classification of 1 was 26.5%, classification of 2 was 53.1%, classification of 3 was 16.8%, and a classification of 4 was 3.5%. African American women had the highest NYHA mean score of 2.25 ($SD = 1.26$), with women of "other" descent having the lowest mean score (1.33, $SD = .82$).

Health care providers also scored the participant's NYHA classification. The overall mean score was 2.43 ($SD = .63$). African American women, women of "other" descent, and Caucasian men had the highest mean scores, 2.50. Men of "other" descent had the lowest mean score, 2.13 ($SD = .35$) (Table 8).

Table 8

*NYHA Classifications and Ejection
Fraction Summary*

	Participant's NYHAs Class	Provider's NYHAs Class	Participant's Ejection Fraction
All Participants (<i>N</i> = 113)	<i>M</i> (<i>SD</i>): 1.96 (.78)	<i>M</i> (<i>SD</i>): 2.43 (.63)	<i>M</i> (<i>SD</i>): 45.82 (14.53)
All Women 33% (<i>n</i> = 37)	<i>M</i> (<i>SD</i>): 1.89 (.77)	<i>M</i> (<i>SD</i>): 2.43 (.56)	<i>M</i> (<i>SD</i>): 48.16 (14.48)
All Men 67% (<i>n</i> = 76)	<i>M</i> (<i>SD</i>): 1.99 (.79)	<i>M</i> (<i>SD</i>): 2.43 (.66)	<i>M</i> (<i>SD</i>): 44.68 (14.51)
African American Women Only 4 % (<i>n</i> =4)	<i>M</i> (<i>SD</i>): 2.25 (1.26)	<i>M</i> (<i>SD</i>): 2.50 (1)	<i>M</i> (<i>SD</i>): 54.25 (21.45)
Caucasian Women Only 24 % (<i>n</i> = 27)	<i>M</i> (<i>SD</i>): 1.96 (.65)	<i>M</i> (<i>SD</i>): 2.41 (.50)	<i>M</i> (<i>SD</i>): 46.44 (14.15)
Women of "Other" Descent 5 % (<i>n</i> = 6)	<i>M</i> (<i>SD</i>): 1.33 (.82)	<i>M</i> (<i>SD</i>): 2.50 (.55)	<i>M</i> (<i>SD</i>): 51.83 (11.48)
Caucasian Men Only 53 % (<i>n</i> = 60)	<i>M</i> (<i>SD</i>): 1.97 (.76)	<i>M</i> (<i>SD</i>): 2.50 (.65)	<i>M</i> (<i>SD</i>): 44.54 (14.78)
African American Men Only 7 % (<i>n</i> = 8)	<i>M</i> (<i>SD</i>): 2.13 (.84)	<i>M</i> (<i>SD</i>): 2.25 (.89)	<i>M</i> (<i>SD</i>): 38.00 (13.95)
Men of "Other" Descent 7 % (<i>n</i> = 8)	<i>M</i> (<i>SD</i>): 2.00 (1.07)	<i>M</i> (<i>SD</i>): 2.13 (.35)	<i>M</i> (<i>SD</i>): 52.38 (10.07)

Health status and HRQOL have been reported to be important indicators for health outcomes in patients with congestive heart failure (Mejhert, Kahan, Persson, & Edner, 2006; Rodriguez-Artalejo et al., 2005). Health status was measured by the SF-36v2, a valid and reliable 36-item instrument used to measure physical and mental health status. (See Table 9 for sample summary.) Physical and mental health summary scores are viewed as separate components, thus the total scores for each are not combined. The SF-36v2 also yields an 8 subscale profile of scores. The SF-36v2 items and scales are scored so that a higher score indicates better health status.

The physical and mental component scores (PCS and MCS) were obtained from the SF36-v2 questionnaire. The overall PCS mean score, of a possible score, for all participants was 37.83 ($SD = 11.24$); and the overall MCS mean score, of a possible score, for all participants was 50.46 ($SD = 12.62$). Examination of the gender and ethnicity/racial groups demonstrated that the highest mean PCS score occurred for men of “Other” descent (39.77, $SD = 14.96$). The lowest mean PCS score was for African American women (31.2, $SD = 9.13$). Men of “Other” descent also had the highest MCS mean score (56.80, $SD = 9.95$); African American men had the lowest mean score (47.05, $SD = 13.09$).

The Minnesota Living with Congestive Heart Failure Questionnaire (MLHFQ) was used to measure health-related quality of life (HRQOL). The MLHFQ is a quality-of-life instrument with reported validity and reliability specifically for heart failure patients. This questionnaire consists of 21 questions with a 6-point Likert-type response scale

where 0 equals *no*, 1 equals *very little*, and 5 equals *very much*. Scores ranged from 0 to 105, with the lower score reflecting a better QOL. However, for this study, the scale was reversed to be consistent with the SF-36v2, the higher the score the better the QOL. When the scores were reversed, the overall mean score of the MLHFQ was 38.73 ($SD = 15.15$). African American men had the highest mean score (45.38, $SD = 16.09$). The lowest score was seen for men of “Other” descent (35.38, $SD = 13.59$) (Table 3).

Table 9

Health Status and HRQOL Scores

	PCS	MCS	MLHFQ
All Participants (N= 113)	<i>M (SD): 37.83</i> (11.24)	<i>M (SD): 50.46</i> (12.62)	<i>M (SD): 38.73</i> (15.15)
All Women 33% (<i>n</i> = 37)	<i>M (SD): 34.50</i> (9.89)	<i>M (SD): 50.89</i> (11.26)	<i>M (SD): 37.91</i> (14.08)
All Men 67% (<i>n</i> = 76)	<i>M (SD): 39.45</i> (11.56)	<i>M (SD): 50.26</i> (13.29)	<i>M (SD): 39.13</i> (15.72)
African American Women Only 4 % (<i>n</i> =4)	<i>M (SD): 31.2</i> (9.13)	<i>M (SD): 48.83</i> (16.65)	<i>M (SD): 39.25</i> (21.85)
Caucasian Women Only 24 % (<i>n</i> = 27)	<i>M (SD): 34.30</i> (10.36)	<i>M (SD): 51.96</i> (9.85)	<i>M (SD): 38.25</i> (10.09)
Women of "Other" Descent 5 % (<i>n</i> = 6)	<i>M (SD): 37.61</i> (8.68)	<i>M (SD): 47.44</i> (14.78)	<i>M (SD): 35.50</i> (24.55)
Caucasian Men Only 53 % (<i>n</i> = 60)	<i>M (SD): 39.72</i> (11.12)	<i>M (SD): 49.81</i> (13.61)	<i>M (SD): 38.80</i> (15.95)
African American Men Only 7 % (<i>n</i> = 8)	<i>M (SD): 37.10</i> (12.59)	<i>M (SD): 47.05</i> (13.09)	<i>M (SD): 45.38</i> (16.09)
Men of "Other" Descent 7 % (<i>n</i> = 8)	<i>M (SD): 39.77</i> (14.96)	<i>M (SD): 56.80</i> (9.95)	<i>M (SD): 35.38</i> (13.59)

Data Analysis

The data analysis related to each of the five research questions (see page 59) is discussed in this section. Prior to statistical analysis directly related to the research questions, the data were screened for missing data, outliers, and assumptions of the statistical tests used. These are discussed prior to the presentation of findings. The statistical analyses used to answer the questions were multivariate analysis of variance (MANOVA), analysis of variance (ANOVA), and hierarchical multiple regression. Additionally, a variety of parametric and nonparametric tests were used to examine sample demographics.

Examination of Data

Prior to the data analyses, the assumptions of the statistical tests were examined. Additionally, all variables were screened for accuracy of data entry and missing values. Errors found due to data entry were corrected.

Missing data. Missing data issues and decisions concerning those issues were made a priori. In cases where the item was independent of others (i.e., not part of a scale), mean substitution was used if not more than 10 cases were missing. The researcher was on site and available when the instruments were completed, and a brief check of completed instruments was conducted; however, there were still some items not answered.

On the General Information Form (GIF), one participant did not rate *perceived symptom management*. This question was independent from all others; therefore the simple group mean imputation was used (Mertler & Vannatta, 2002).

An additional question on the MLHFQ was part of the total scale score, however, it was not part of a subscale. This question that asked about money for medical care was left blank by 3 participants, more than occurred for any other question on any of the instruments. Simple mean imputation was not performed for this item due to its individual nature (Fayers, Curran, & Machin, 1998). There was one participant who omitted a question concerning side effects from treatment. Again, a simple mean imputation was not appropriate for this item. The only other question missed with more frequency than one per group, was the missed question of loss of self-control ($n = 2$). Because this question belonged to a subscale of the emotional dimension score, simple mean imputation was performed. For the 4 participants who did not have total MLHFQ scores, the simple group mean was used for their score (Mertler & Vannatta, 2002).

Three participants did not answer 8 questions on the SF36v2; the occurrence of this missing data was apparently either random, based on individual decisions not to answer, or because they were simply overlooked. Mean imputation was used with 2 of the participants' questions. For the third, who answered only 1 of the 5 subscale questions, the group mean for the subscale score was input (Mertler & Vannatta, 2002). Overall, less than 2% of all items were missing.

Outliers. Evaluation of the data for outliers was comprehensive. Variables were screened for outliers using frequency distributions, box-plots, and histograms. The instruments were evaluated for univariate outliers by visual examination of q-q plots, and box plots. Participants' data were not normally distributed on some demographic variables (i.e., perceived symptom management, total number of comorbidities,

household income and house value). Age, total number of comorbidities, perceived general health status, perceived symptom management, household income and house value had outliers; however, the ratings and numbers were believed not to be in error. The PCS had no outliers; however, the MCS (n= 1) and MLHFQ (n = 3) had only a few. These values are considered important to the population being studied and are vital to the finding of new knowledge (Burns & Grove, 2005). None of the participant scores, therefore, were removed.

Normality. The assumption of normality was evaluated using both univariate and multivariate methods. Both, graphical and statistical methods were used. As previously discussed, the data appeared to be skewed due to outliers that were identified as individual differences and not errors in data collection or analysis.

Pearson's Skewness Coefficient was used to assess symmetry or to see if the data were normally distributed. If data for a variable are asymmetrical, they are skewed (Munro, 2001). Pearson's Skewness Coefficient was calculated using a nonalgebraic formula: $Skewness = (mean - median)/SD$ (Munro). This formula was used for all continuous variables in this study. The values fell between -1 and +1 SD units, indicating that these distributions were not substantially skewed (See Table 10 for Pearson's Skewness Coefficients).

Further analysis was conducted using Kolmogorov-Smirnov (K-S) test to determine whether the distributions of selected variables were significantly different from normal distributions. Departure from normality is indicated if the computed value is significant (Field, 2005). Physical component score (PCS) and age were not significant

(Table 10 for K-S). However, the mental component score (MCS), Minnesota Living with Heart Failure Questionnaire (MLHFQ), total number of comorbidities, perceived general health status, and perceived symptom management were significant. The data appear to be skewed due to individual differences and not errors in data collection or analysis. Outliers were removed to see if it would make a difference in the K-S statistic; it did not.

Skewness was examined using descriptive statistics. The results are listed in Table 10. For skewness, a value that did not fall between -1 or +1 would indicate a substantially skewed distribution (Munro, 2001).

Table 10

Normality Data

	Pearson's Skewness Coefficient	SPSS Skewness	Kolmogorov- Smirnov (<i>p</i>)
Physical Component Score (PCS)	.173	.032	.098
Mental Component Score (MCS)	-.299	-.784	.000
Minnesota Living With Heart Failure Questionnaire	.180	.689	.002
Perceived Symptom Management	.090	-.694	.000
Age	-.05	-.265	.151
Total Number of Comorbidities	.189	.883	.000
Perceived General Health Status	-.192	.098	.000

Homogeneity of variance. The assumption that there are equal variances among groups (i.e., homogeneity of variance) is a requirement of most statistical tests comparing means. Levene's test was used to test variances in the groups (Field, 2005). The results suggested equality of variance for each variable between groups (see Table 11), with the exception of living status which was significant, $p = .027$.

Table 11

*Levene's Test of Equality of Error
Variances*

	F	df1	df2	p
Age	.073	1	111	.787
Perceived general health status	.771	1	111	.382
Perceived symptom management	.000	1	111	.999
PCS	3.274	1	111	.073
MCS	1.041	1	111	.310
Total number of comorbidities	.585	1	111	.446
Living Status	4.999	1	111	.027
Ethnicity/Race	.419	1	111	.519
MLHFQ	2.221	1	111	.139

Data Analysis of Research Questions

In this section, each statistical test that was used to answer the five research questions will be discussed. Tests that were used were MANOVA (Question 1), independent *t* tests and chi-square as appropriate to the level of data (Question 2), hierarchical multiple regression analysis (Questions 3 and 4), and kappa statistic (Question 5).

Findings Related to Multivariate Analysis of Variance

One-way MANOVA was conducted to address the first research question: Are there differences in self-reported health status and HRQOL of men and women with a diagnosis of CHF? The dependent variables were two instruments that were used in the research study, the MLHFQ and the SF36v2 and the independent variable was gender.

Missing data were replaced using group means. Pre-analysis data screening was conducted to make certain the assumptions of MANOVA testing were met. Tests of normality using skewness and Kolmogorov-Smirnov statistic indicated that data were normally distributed (Table 10). Homogeneity of variance was assessed using Levene's Test. The results demonstrated equality of variance for each variable between groups (see Table 11). Homogeneity of covariance was evaluated within MANOVA by calculating Box's Test of Equality of Covariance Matrices. The Box's Test results using these specific variables reveals that equal variances can be assumed (Box's $M = 5.833$, $F(6, 33673.562) = .938$, $p = .466$. Wilks' Lambda (Λ) was used as the multivariate test statistic (Table 12). Based on the results of pre-analysis data screening, no transformation

was done to any of the dependent variables, nor was any case eliminated. A list of variables and the variable name of each as used in SPSS is provided in Table 13.

Table 12

Box's Test of Equality of Covariance Matrices

Box's M	F	df1	df2	p
5.833	.938	6	33673.562	.466

Table 13

SPSS Variables

SPSS Variable Name	Variable Name
PCS	Physical Component Score
MCS	Mental Component Score
MMLHFQTO	Minnesota Living with Heart Failure Questionnaire Total Score
AGE	Age
ETH_MOD	Ethnicity/Race modified score
TOT_COMO	Total number of Comorbidites
LIVEMOD	Living status modified score
Gender	Gender

A one-way MANOVA was conducted to determine the effect of gender differences on health status (PCS and MCS) and health-related quality of life (MMLHFQTO). Table 14 presents means and standard deviations for the three outcome measures.

MANOVA results revealed no significant differences among gender categories on the dependent variables, Wilks' $\Lambda = .082$, $F(3,109.000) = 2.29$, $p = .082$, multivariate $\eta^2 = .059$. Analysis of variance (ANOVA) was conducted on each dependent variable as a follow-up test to MANOVA. Gender category differences were significant for PCS, $F(1, 111) = 4.997$, $p = .027$, partial $\eta^2 = .043$. Differences in MCS and MMLHFQTO were not significant, $F(1, 111) = .061$, $p = .805$, partial $\eta^2 = .001$ and $F(1, 111) = .160$, $p = .690$, partial $\eta^2 = .001$ (Table 15 and 16).

Table 14

*Means and Standard Deviations for PCS,
MCS, and MMLHFQTO*

				95%	CI
				Lower Bound	Upper Bound
	Gender	Mean	SE		
PCS	Female	34.498	1.815	30.901	38.096
	Male	39.447	1.267	36.937	41.957
MCS	Female	50.886	2.083	46.759	55.013
	Male	50.257	1.453	47.377	53.136
MMLHFQTO	Female	37.913	2.500	32.958	42.867
	Male	39.133	1.745	35.676	42.590

Table 15

*MANOVA Multivariate
Table*

Effect		Value	<i>F</i>	Hypothesis (df)	Effor (df)	<i>p</i>	Partial Eta Squared
Intercept	Pillai's Trace	.978	1646.567	3.000	109.000	.000	.978
	Wilk's Lambda	.022	1646.567	3.000	109.000	.000	.978
	Hotelling's Trace	45.318	1646.567	3.000	109.000	.000	.978
	Roy's Largest Root	45.318	1646.567	3.000	109.000	.000	.978
GENDER	Pillai's Trace	.059	2.294	3.000	109.000	.082	.059
	Wilk's Lambda	.941	2.294	3.000	109.000	.082	.059
	Hotelling's Trace	.063	2.294	3.000	109.000	.082	.059
	Roy's Largest Root	.063	2.294	3.000	109.000	.082	.059

Table 16

*MANOVA Univariate
Test Results*

<i>Source</i>	<i>Dependent Variable</i>	<i>Type III Sum of Squares</i>	<i>Df</i>	<i>Mean Square</i>	<i>F</i>	<i>P</i>	<i>Partial</i>
Correcte Model	PCS	609.333	1	609.333	4.997	.027	.043
	MCS	9.857	1	9.857	.061	.805	.001
	MMLHFQTO	37.074	1	37.074	.160	.690	.001
Intercept	PCS	136067.857	1	136067.857	1115.868	.000	.910
	MCS	254571.063	1	254571.063	1586.294	.000	.935
	MMLHFQTO	147719.210	1	147719.210	638.583	.000	.852
GENDER	PCS	609.333	1	609.333	4.997	.027	.043
	MCS	9.857	1	9.857	.061	.805	.001
	MMLHFQTO	37.074	1	37.074	.160	.690	.001

Independent Samples t-tests

Independent-samples *t* tests and chi square were used to evaluate the variables of Question 2: Are there differences in specified variables (i.e., age, race/ethnicity, living status, number of comorbidities, perceived general health status, and perceived symptom management) of men and women with a diagnosis of CHF?

Independent-samples *t* tests were conducted to evaluate whether there were differences in age, number of comorbidities, perceived general health status, and perceived symptom management of men and women with heart failure. Levene's test was not significant for age ($p = .787$), total number of comorbidities ($p = .446$), perceived general health status ($p = .382$), perceived symptom management ($p = .999$); therefore, the assumption of equality of variance was met. The independent-samples *t* tests were not significant for age, $t(111) = 1.756, p = .082$, for total number of comorbidities, $t(111) = 1.621, p = .108$, for perceived general health status, $t(111) = 1.188, p = .237$, and for perceived symptom management, $t(111) = -.947, p = .346$. Though not a significant difference in age, females ($M=71.19, SD = 12.092$) had a higher mean age than males ($M = 67.05, SD = 11.583$) (Tables 17 and 18).

Table 17

Gender Specific Mean, Standard Deviation and Standard Error for Certain Variables

	Gender	N	<i>M</i>	<i>SD</i>	Std. Error <i>M</i>
Age	Female	37	71.19	12.092	1.988
	Male	76	67.05	11.583	1.329
Total Number of Comorbidities	Female	37	3.76	1.862	.306
	Male	76	3.16	1.833	.210
Perceived General Health Status	Female	37	2.97	.928	.152
	Male	76	2.75	.940	.108
Perceived Symptom Management	Female	37	6.92	2.373	.390
	Male	76	7.34	2.157	.247

Table 18

Independent Samples t Test
Results

		Levene's Test for Equality of Variance		t-test for Equality of Means		
		F	p	t	df	p (2-tailed)
Age	Equal variances assumed	0.73	.787	1.756	111	.082
	Equal variances not assumed			1.730	68.760	.088
Total Number of Comorbidities						
Equal variances assumed		.585	.446	1.621	111	.108
Equal variances not assumed				1.612	70.470	.111
Perceived general health status						
Equal variances assumed		.771	.382	1.188	111	.237
Equal variances not assumed				1.194	72.311	.236

Table 18 (Continued)

Independent Samples Test Results

		t-test for	Equality of Means	95% Confidence of the	Interval Difference
		Mean Difference	Std. Error Difference	Lower	Upper
Age	Equal variances assumed	4.14	2.355	-.531	8.804
	Equal variances not assumed	4.14	2.391	-.634	8.907
Total Number of Comorbidities					
	Equal variances assumed	.60	.369	-.133	1.331
	Equal variances not assumed	.60	.371	-.142	1.339
Perceived general health status			.188	-.149	.595
	Equal variances assumed	.22			
	Equal variances not assumed	.22	.187	-.149	.595

Table 18 (Continued 2)

*Independent Samples t Test
Results*

		Levene's Test for Equality of Variance		<i>t</i> -test for	Equality of Means	
		<i>F</i>	<i>p</i>	<i>t</i>	df	<i>p</i> (2-tailed)
97	Perceived symptom management					
	Equal variances assumed	.000	.999	-.947	111	.346
	Equal variances not assumed			-.916	65.693	.363

Table 18 (Continued 3)

Independent Samples Test Results

		<i>t</i> -test for	Equality of Means	95% Confidence of the	Interval Difference
		Mean Difference	Std. Error Difference	Lower	Upper
98	Perceived symptom management Equal variances assumed	-.42	.447	-1.309	.463
	Equal variances not assumed	-.42	.462	-1.346	.499

Chi Square Test Results for Research Question 2

A two-way contingency table analysis was conducted to evaluate whether there was a difference in gender and living status in men and women with a diagnosis of CHF. The two variables were (a) gender with two levels (female and male) and (b) living status (living alone or living with someone). Gender and living status were found to be independent, $\chi^2(1, N = 113) = 1.331, p = .249$.

A second contingency table analysis was conducted to evaluate whether there was a significant difference in gender and ethnicity/race groups. The two variables were (a) gender with two levels (female and male) and (b) ethnicity/race groups with three levels (white (Caucasian), black (African-American), and other). Gender and race/ethnicity were found to be independent of each other, $\chi^2(2, N = 113) = .768, p = .681$.

Hierarchical Multiple Regression Test Results for Research Question 3

Hierarchical multiple regression analysis was utilized to answer both Research Questions 3 and 4. The assumptions for multiple regression are applicable to both questions. Following discussion of the testing of these assumptions, the results of Question 3 will be presented. Research Question 4 will be discussed in the following section.

Prior to performing this analysis, relationships of the independent variables with the dependent variable were tested using point biserial correlation and Pearson r to determine whether any demonstrated low or multicollinear relationships. Based on low correlations, gender, race/ethnicity, and living status were removed from the questions. Tabachnick and Fidell (1996) state that moderate violations of linearity and homoscedasticity only

weaken the regression analysis. Research Question 3, revised, was: Are age, number of comorbidities, perceived general health status, perceived physical health status, perceived mental health and perceived symptom management significant predictors of HRQOL? Hierarchical multiple regression was selected to allow the researcher to select the order in which each variable is entered into the analysis. The regression analysis was performed with HRQOL as the dependent variable (DV) and the six researcher-selected predictors as independent variables (IV). The six predictors included age, number of comorbidities, perceived general health status, perceived physical health status, perceived mental health status and perceived symptom management.

The study's conceptual framework, Wilson and Cleary's (1995) health-related quality of life conceptual model provided the foundation for testing. Research Questions 3 and 4 examine the relationships among overall quality of life and other constructs as depicted in the Model (see Figure 1, p. 6). A review of the literature provided the basis for model testing. The research questions were tested using sequential multiple regression (Hierarchical multiple regression or Blockwise Entry). This approach, using the technique of multiple regression, examines theoretically predicted relationships among constructs. In hierarchical multiple regression, the researcher enters known predictors into the model first based on their importance in predicting the outcome (Field, 2005). Mertler and Vannatta (2002) state that multiple regression analysis allows the researcher to examine the contribution of the model's variables to the prediction of the dependent variable.

Data were tested as part of the regression analysis to assess the adequacy of fit between the data and the assumptions of regression process. Multicollinearity was assessed by examining bivariate correlations. Criteria used to measure against were the tolerance statistic ($\leq .1$) and the variance inflation factor (VIF) (> 10) (Mertler & Vannatta, 2002). As shown in Table 19, preliminary collinearity regression showed that multicollinearity was not assumed, indicating that a strong relationship did not exist between two or more of the predictors in this regression model (Field, 2005).

Linearity between IVs and the specific DV using the scatterplot matrix of IVs and specific DV at each model stage was assessed by the researcher. Multivariate normality and homoscedasticity (i.e., the variances of the residuals for the predictors variables are similar) were examined using residuals plots. The assumptions for conducting the regression analysis were partially met.

Homoscedasticity

Homoscedasticity was examined in the regression analysis using scatterplots. The scatterplots show the residuals that are plotted against the predicted value, which in this study was health-related quality of life (HRQOL). The scatterplot showed a violation of the assumption of homoscedasticity. The predicted values width was narrow at small predicted values for the dependent value and increased in width as the dependent values increased. This pattern demonstrated a lack of constant variance, or heteroscedasticity. According to Tabachnick and Fidell (1996), this moderate violation may weaken the regression analysis, however it does not invalidate the analysis.

Table 19

Tests for Multicollinearity

Independent variable	Dependent variable	Tolerance	VIF
Total number of comorbidities	Perceived symptom management	.997	1.003
Age	Perceived symptom management	.997	1.003
Perceived Symptom Management	PCS	1.00	1.00
Perceived Symptom Management	MCS	1.00	1.00
PCS	Perceived General Health Status	.978	1.023
MCS	Perceived General Health Status	.978	1.023
Perceived General Health Status	MMLHFQTO	1.00	1.00
Total Number of Comorbidities	MMLHFQTO	1.00	1.00
Age	MMLHFQTO	1.00	1.00

Hierarchical regression analysis was used to test the paths in the model with successive multiple regression equations calculated to estimate path coefficients. The DV was regressed onto the IVs at each stage of the model testing, which allowed them to be connected to the DV. The DVs in the model included, in order of staging: (a) Perceived symptom management, (b) Physical component score (PCS) and Mental component score (MCS), (c) Perceived general health status, and (d) Minnesota Living with Heart Failure Questionnaire total score (MMLHFQTO). The independent variables in the total model included: (a) age and total number of comorbidities at Stage 1, (b) Perceived symptom management at Stage 2, (c) PCS and MCS at Stage 3, and (d) Perceived general health status at Stage 4. The dependent variable (HRQOL) represented Stage 5.

In the initial regression analysis, SPSS casewise diagnostics listed two cases that were seen as outliers with standardized residuals greater than -3.0. After a closer examination of each participant's individual scores and their effects on the overall regression, the decision was made to leave these cases in the analysis.

Using hierarchical multiple regression, path coefficients were estimated by entering the predictors for each dependent variable in the model. Coefficients were estimated by simultaneous entry of predictors for each hypothesized DV in the model, and the standardized betas for each path are given in Figure 2. The results of each of the five regression equations in the model are also summarized in Table 20. Standardized Betas (β) are given for each path (Table 21). The amount of DV variance that can be explained by the combination of the IVs is expressed as the R^2 .

Table 20

Summary of Hierarchical Multiple Regression Analysis for Predicting Variables (N=113)

Predictor Variable(s)	Dependent Variable	R	R ²	R ² adj	Std. Error Estimate
Stage 1					
Age and Total Number of Comorbidities	Perceived Symptom Management	.409	.167	.152	2.05
Stage 2					
Perceived Symptom Management	PCS	.392	.153	.146	10.39
	MCS	.488	.238	.231	11.06
Stage 3					
MCS,PCS	Perceived General Health Status	.548	.301	.288	.791
Stage 4					
Perceived General Health Status	MMLHDQTO	.192	.037	.028	14.94
Stage 5					
Total Number of Comorbidities	MMLHDQTO	.149	.022	.013	15.05
Age	MMLHDQTO	.205	.042	.034	14.9

Table 20 (Continued)

Summary of Hierarchical Multiple Regression Analysis for Predicting Variables (N=113)

Predictor Variables	Dependent Variables	R ² chg	Fchg	Sig.	df ₁	df ₂
Stage 1						
Age and Total Number of Comorbidities	Perceived Symptom Management	.167	11.030	.000	2	110
Stage 2						
Perceived Symptom Management	PCS	.153	20.11	.000	1	111
	MCS	.238	34.68	.000	1	111
Stage 3						
MCS,PCS	Perceived General Health Status	.301	23.65	.000	2	110
Stage 4						
Perceived General Health Status	MMLHDQTO	.037	4.26	.041	1	111
Stage 5						
Total Number of Comorbidities	MMLHDQTO	.022	2.51	.116	1	111
Age	MMLHDQTO	.042	4.89	.029	1	111

Table 21

*Coefficients for Hierarchical
Multiple Regression Analysis
(N=113)*

Predictor Variable	Dependent Variable	B	SE B	β	t	Sig.
Stage 1						
Total Number of Comorbidities	Perceived Symptom Management	-.397	.105	-.331	-3.79	.000
Age		4.170E-02	.016	.222	2.55	.012
Stage 2						
Perceived Symptom Management	PCS	1.98	.440	.392	4.48	.000
	MCS	2.76	.469	.488	5.89	.000
Stage 3						
PCS	Perceived General Health Status	3.34E-02	.007	-.400	4.97	.000
MCS		2.38E-02	.006	-.320	3.97	.000
Stage 4						
Perceived General Health Status	MMLHDQTO	-3.11	1.51	.192	-2.06	.041

Table 21 (Continued)

*Coefficients for Hierarchical
Multiple Regression Analysis
Variables (N=113)*

Predictor Variable	Dependent Variable	B	SE B	β	t	Sig.
Stage 5						
Total Number of Comorbidities	MMLHDQTO	1.21	.766	.149	1.583	.116
Age	MMLHDQTO	-.263	.119	-.205	-2.21	.029

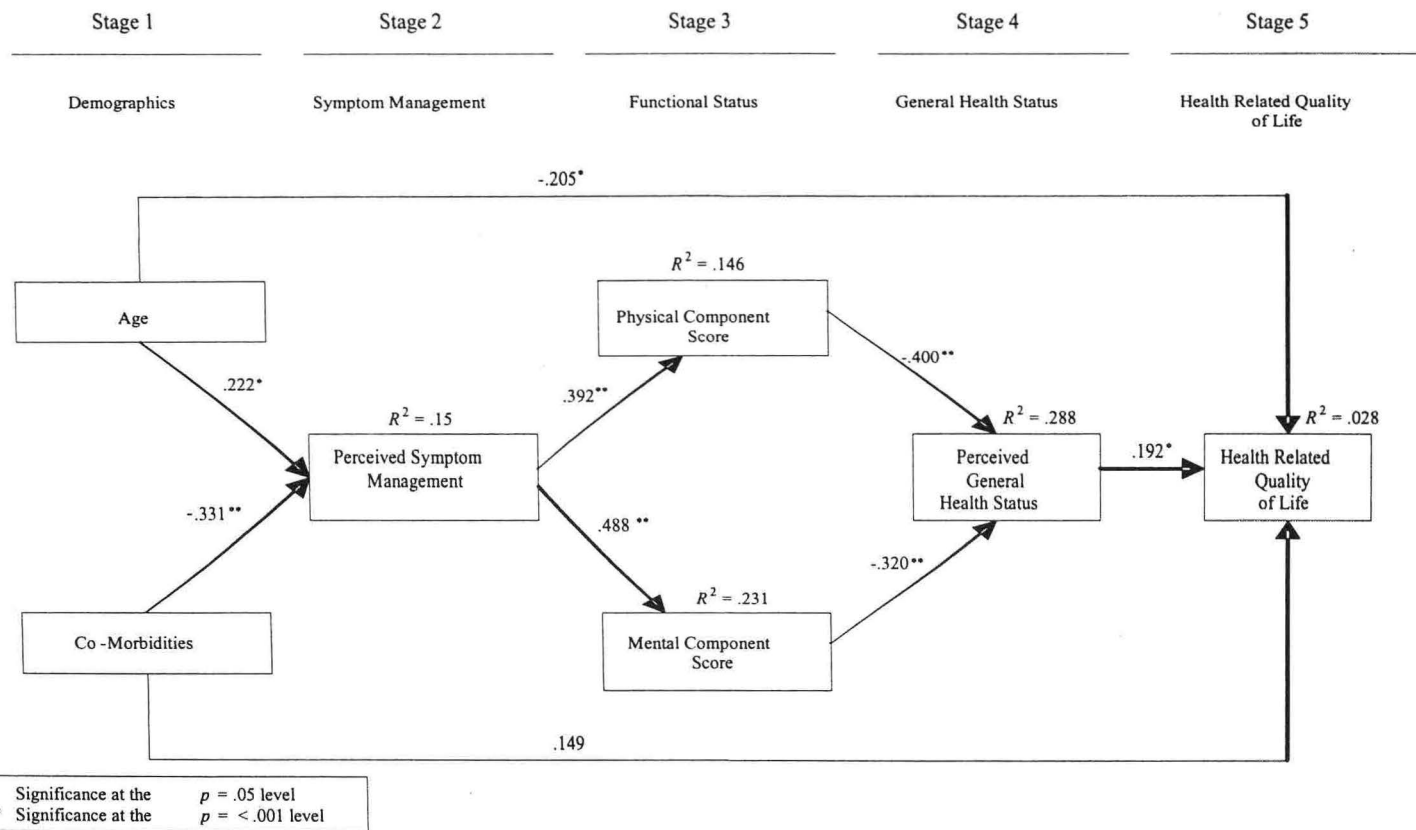


Figure 2. Conceptual model of predictors to health-related quality of life with empirical findings.

According to Mertler and Vannatta (2002), path analysis is a technique that is used under the broad heading of causal modeling. Path analysis is used to examine the relationships between a set of independent variables and a dependent variable (Munro, 2001). Simple regression techniques are the bases of the path analysis. However, path analysis allows the researcher to examine these relationships a step further than the traditional use of multiple regression. Path models are considered a type of “causal model” (Munro, 2001). Figure 2 illustrates the path model for this research study. It demonstrates the theorized, directional relationships among this set of variables. Prior knowledge and theories are the underpinnings for the connection among the variables in the model, not statistical techniques (Polit, 1996). The independent variables (IV) may have a direct or indirect effect on the dependent variable (DV), depending on the hypothesized path. Regression analysis is used for the analysis of path models and each dependent variable is, in turn, regressed on the variables affecting it.

The sum of the direct and indirect effects is the total effect (Pedhazur & Schmeklin, 1991). Path analysis provides information pertaining to the consistency between the data and the theorized path model. This is accomplished by analyzing all the paths. However, if the data do not fit the theorized relationships in the model, this may warrant a revision in the model (Munro, 2001). According to Mertler and Vannatta (2002), path analysis is an extension of multiple regression; therefore, the assumptions that were discussed previously in this chapter for multiple regression are also appropriate here.

Path analysis was conducted to examine the hypothesized paths in the model with successive multiple regression equations calculated to estimate path coefficients. During each stage of the model testing the DV was regressed onto the IVs that were linked to the DV. The DVs in the model included (a) Health related quality of life (MMLHDQTO); (b) Perceived general health status (PGHS); (c) Health status (i.e. physical component score (PCS) and mental component score (MCS); and (d) Perceived symptom management (PSM). Independent variables in the model included: (a) PGHS; (b) Health status (i.e. PCS and MCS); (c) PSM; (d) Age; and (e) Total number of co-morbidities.

The results of each of the five regression equations, and seven paths in the model are summarized in Table 22. Listed in the table are the standardized Beta (β) weights for each hypothesized path and the R^2 revealing the amount of variance explained for each of the model's staged dependent variables. Figure 2 provides a visual depiction of the model, giving the standardized betas for all hypothesized paths.

Table 22

Regression Analysis Calculated to Determine Path Coefficients in the Hypothesized Model

Outcome Variable	R ²	Predictor Variables	β	p
Health Related Quality of Life (MMLHDQTO)	.028	Perceived General Health Status (PGHS)	.192*	.041
PGHS	.288	Physical Component Score (PCS)	-.400*	.000
		Mental Component Score (MCS)	-.320**	
PCS	.146	Perceived Symptom Management (PSM)	.392**	.000
MCS	.231		.488**	.000
PSM	.152	Age	.222*	.000
		Total Number of Co- Morbidity	-.331**	
MMLHDQTO	.034	Age	-.205*	.029
	.013	Total Number of Co- Morbidity	.149	.116

* Significant at the p = .05 level

** Significant at the p = < .001 level

Regression results, based on the path analysis, indicate an overall model of six variables (i.e., age, number of comorbidities, perceived symptom management, PCS, MCS and perceived general health status) that directly and indirectly influence HRQOL. Age and number of comorbidities are projected to have both direct and indirect paths to HRQOL, and their direct influence only accounted for approximately 2% of the variance in the dependent variable. The number of comorbidities was not in the predicted direction and was not a significant predictor of HRQOL. Age ($\beta = -.205, p = .029$) was a weak predictor. All other model variables were significant and, all but three were in the direction predicted (see Figure 2, p. 108). The Standardized Betas for the indirect paths from PGHS, PCS, MCS, PSM, age, and number of comorbidities were .192, -.400, -.320, .392, .488, .222, and -.331 respectively. PGHS, the persons perceived health status showed only a slight influence ($\beta = .192$) on HRQOL.

Research Question 3 was supported by the all of the tested paths in the model, except the direct path from comorbidities to HRQOL. Though the computed Beta was significant for PGHS, this relationship was weak.

Research Question 4

Research Question 4, revised, was: Do symptom status (i.e., perceived symptom management), functional status (i.e., perceived physical health status and perceived mental health status), and general health perceptions (i.e., perceived general health status) serve as mediating variables between the exogenous variables (i.e., age and comorbidities) and overall quality of life. To determine whether the variables at Stages 2, 3, and 4 of the model served as mediators between the exogenous variables of age and comorbidities and

the dependent variable of HRQOL, the indirect paths were computed to determine whether their placement in the model increased the total effect. Table 23 shows the direct and indirect paths, along with the total effect of age and comorbidities. The total effect for age and comorbidities increases, but the increase for comorbidity is slight.

Explanation of computation for age was: $(.222) (.392) (-.400) (.192) + (.222) (.488) (-.320) (.192) = -.006683 + -.006656 = -.013$. Computation for comorbidities was: $(-.331) (.392) (-.400) (.192) + (-.331) (.488) (-.320) (.192) = .009964 + .009924 = .0199 = .020$.

Table 23

Direct and Indirect Paths

Exogenous Variable	Direct + Indirect	Total Effect
Age	-.205 + -.013	-.218
Comorbidities	.149 + .020	.169

Research Question 5

The kappa statistic was used to evaluate Research Question 5: Is there agreement of the New York Heart Association's (NYHA) Functional Class ratings made by the participant and his/her health care provider? The agreement between the health care provider's scoring of the New York Heart Association's classification and the participant's scores of the same classification were examined. The Kappa statistic was computed using the following formula: $K = Po - Pc / 1 - Pc = .44 - .37 / 1 - .37 = .11$.

Observer agreement (Po) was found by $1 + 35 + 12 + 2 / 113 = .44$. Chance agreement (Pc) was found by $(3) (30) / 113^2 + (63) (60) / 113^2 + (42) (19) / 113^2 + (5) (4) / 113^2 = .37$

(Fleiss, 1971; Pett, 1997). The percentage of interobserver agreement was 44% and the proportion of chance agreement was 37%. A kappa coefficient and obtained value of .11, $p = .018$, shows a poor agreement between patients and providers, using the criteria of Fleiss (1971). The significance of .018 rejects the null hypothesis that $\text{kappa} \leq 0$. The agreements were beyond chance level.

Summary

This chapter has presented the study results using an exploratory cross-sectional design which examined groups of participants at a certain moment in time (Polit & Beck, 2003). The results per MANCOVA indicate statistical significance in total number of comorbidities with respect to health status and HRQOL. Specifically, it was found that the total number of comorbidities was significant for PCS and not MCS.

The results from the independent samples t tests, ANOVA, and chi-square indicated that there was not a statistically significant difference in gender on specified variables (i.e., age, race/ethnicity, living status, number of comorbidities, perceived general health status, and perceived symptom management) in a sample of patients with a diagnosis of CHF. Gender, therefore, was removed from further model testing when looking at HRQOL.

Regression results, using a path analysis approach, indicated an overall model of six predictors (i.e., perceived symptom management, health status (PCS and MCS), perceived general health status, age, and total number of comorbidities) that directly and indirectly influence HRQOL. Age, but not comorbidities, was found to be a significant exogenous variable in the model with a direct causal link to HRQOL. Perceived general

health status, physical health status, mental health status, and perceived symptom management were found to mediate HRQOL. Symptom status (i.e., perceived symptom management), functional status (i.e., perceived physical health status and perceived mental health status), and general health perceptions (i.e., perceived general health status) served as mediating variables between the exogenous variable of age and health-related quality of life in persons with CHF. Findings related to the placement of the number of comorbidities in the model were unclear.

CHAPTER V

DISCUSSION OF FINDINGS

In order to help adults improve their quality of life (QOL) while living with congestive heart failure (CHF), it is important for health care providers to learn more about differences between the genders, as well as factors that may contribute to their QOL. Quality of life is used as a key indicator of the effectiveness of medical treatment in adults diagnosed with CHF. A primary goal of *Healthy People 2010* is improving people's QOL and overall well-being (U. S. Department of Health and Human Services [DHHS], 2000).

This chapter discusses the interpretation and significance of the results presented in the previous chapter. A summary of the study will be discussed. Discussion of the sample characteristics and findings from the research questions follow. Conclusions and implications is the next section. Recommendations for future study are then presented.

Summary of the Study

The purpose of this study was to examine the health status and health-related quality of life (HRQOL) of men and women with a diagnosis of CHF. The specific aims for the study, as initially identified, were to determine whether (a) there were differences in self-reported health status and HRQOL of men and women with CHF, (b) the variables of age, race/ethnicity, living status, number of comorbidities, perceived general health status, and perceived symptom management differ by gender, and (c) gender, age, race,

number of comorbidities, living status, perceived general health status, perceived symptom management, perceived physical health status, and perceived mental health status predict HRQOL.

The research questions, modified slightly as the research and data analysis progressed, were as follows:

Research Question 3: Are age, number of comorbidities, perceived general health status, perceived physical health status, perceived mental health and perceived symptom management significant predictors of HRQOL?

Research Question 4: Do symptom status (i.e., perceived symptom management), functional status (i.e., perceived physical health status and perceived mental health status), and general health perceptions (i.e., perceived general health status) serve as mediating variables between the exogenous variables (i.e., age and comorbidities) and overall quality of life.

A cross-sectional exploratory research design was used to answer the specific research questions at a certain moment in time. A convenience sample included 113 men and women with a diagnosis of CHF who were attending a cardiology clinic. Variables tested included gender, age, race/ethnicity, living status, number of comorbidities, perceived general health status, perceived symptom management, health related quality of life (HRQOL), and health status (physical and mental components). The study participants met the inclusion criteria for enrollment in the study. They attended a cardiac clinic, had documented CHF, and their ages ranged from 40 to 95 years of age. Data were collected with three paper-and-pencil measurements: the General Information Form (GIF)

developed for the study, the SF-36 Health Survey Version 2.0 (SF-36v2), and the Minnesota Living with Congestive Heart Failure (MLHFQ) As previously discussed in Chapter 3, these latter two questionnaires have demonstrated strong validity and reliability.

Health status and HRQOL have been documented in the literature as important variables for individuals living with a chronic condition. Limited research related to these variables has been conducted with CHF patients, including whether there are gender differences. Also, little is known about the predictors of HRQOL for persons with CHF.

Health status and HRQOL were evaluated using two different self-report instruments. The Minnesota Living with Heart Failure Questionnaire (MLHFQ) was used to measure HRQOL. The Medical Outcomes Study Health Survey, Version 2.0 (SF-36v2) measured health status. These measures were given to the participants at one point in time during a clinic visit. A general information form (GIF) was also given to the participants to gather demographics and evaluate perceived general health status, symptom management, ejection fraction, and New York Heart Association's classification. Also, the GIF included questions about comorbidities, certain medications, the time of the last hospitalization, and which symptoms prompted the patient to go to the hospital.

The participants' responses obtained from all three questionnaires were placed in an SPSS data file. Participants' data on the outcome variables were evaluated against explicit research questions using multivariate analysis of variance (MANOVA),

independent *t* tests, chi square, hierarchical multiple regression analysis, and kappa statistic.

Missing data were replaced using group means. Following recoding of the MLHFQ scores, data analyses were initiated. The average age of the participants was 68.41 years. The majority of participants were male ($n = 76$), Caucasian ($n = 87$), lived with someone ($n = 95$), perceived their general health status to be “Good” or better ($n = 69$) and had not been hospitalized within the last year ($n = 69$). The average total number of comorbidities was 3.35. The symptom most often prompting them to go to the hospital was shortness of breath ($n = 37$).

The analyses for Research Question 1 revealed no significant differences among gender categories on the dependent variables measuring health status using the SF-36v2 (physical component score {PCS}, mental component score {MCS}) and the health-related quality of life (Minnesota Living with Congestive Heart Failure).

For Research Question 2, independent-samples *t* tests were not significant for age, total number of comorbidities, perceived general health status, and perceived symptom management. Chi square test results revealed that gender and living status were independent, as were gender and race/ethnicity. Based on the findings for Questions 1 and 2, the independent variables of gender, living status, and race/ethnicity were removed from the regression analysis which followed for Questions 3 and 4.

For Research Question 3, hierarchical regression analysis showed all predictors for each hypothesized dependent variable in the model contributed to the outcome.

Perceived symptom management (PSM) was a direct predictor of functional status, and

its prediction of the mental health component of functional status ($\beta = .488$) represented the model's highest relationship. The only nonsignificant path in the model was the direct prediction of HRQOL by the number of comorbidities. Two of the model's paths (see Figure 2, page 108) were not in the expected direction. Comorbidities to HRQOL was positive, rather than negative, and perceived general health status to HRQOL was negative, rather than positive.

The analyses for Research Question 4 showed that the variables between age and HRQOL serve as mediating variables, though they do not contribute to the outcome when comorbidities is the exogenous variable. In other words, the variables of perceived general health status, physical health status, mental health status, and perceived symptom management contributed to the outcome of HRQOL when age, but not comorbidities, was the exogenous variable.

Research Question 5 examined the agreement between patients and their health care providers regarding their Functional Class rating using the rating scale of the New York Heart Association. Using kappa statistic, only 44% agreement between patients and provider was found, adjusted to 37% for chance agreement.

The findings from this study will be discussed thoroughly in the next section of this Chapter. There are limited generalizations when a small nonprobability sample is drawn from a specific population. This may lead to a Type II error. However, the results of this study suggested variables that contribute to quality of life in people with CHF. Also, the study showed a poor level of agreement between the participants' perceptions

of their New York Heart Association's (NYHA) function classification as compared to that of their health care providers.

Discussion of the Findings

Sample Characteristics

The sample characteristics in this study are similar to other studies. As is the case in studies reported in the literature, the majority of participants in this study were male (Cowie et al., 2002; Gott et al., 2006; Gottlieb et al., 2004; Juenger et al., 2002) and Caucasian (Lafata, Pladevall, Divine, Heinen, & Philbin, 2004).

Age. The mean age of participants was approximately 68 years. Women had a higher mean age 71.19 than did men, 67.05. These findings are similar to Chin, Zhang, and Rathouz (2003) and Chin and Goldman (1998). This reflects the lower incidence of coronary heart disease in women (Ho, Pinsky, Kannel, & Levy, 1993). However, this statistic changes as age increases beyond the age of 75 (Friedman, 1993). Kimmelman and Konstam (1995) found that women were significantly older than men when diagnosed with CHF (72 versus 68 years). Vaccarino, Chen, Wang, Radford, & Krumholz (1999) found that women tend to live longer after a diagnosis of CHF than men. This could be due to estrogen use in ageing women (Reis et al., 2000).

Living arrangement. The majority of participants lived with someone. These findings are similar to those of other studies (Gott et al., 2006). Men were more likely to live with someone than were women. These findings were similar to the findings of Kim et al (2000) where fewer women than men were married. In a study by Hamner and Ellison (2005), patients who lived with family, other than in a facility, were associated

with readmissions. In a study by Luttik, Jaarsma, Veeger, and van Veldhuisen (2006), patients living alone were consistently lower on their QOL scores than those living with a partner.

Comorbidities. Sixty percent of participants had at least 3 comorbidities. These findings are similar to a study conducted by Gott et al. (2006). In that study, 69% of participants experienced two or more comorbidities in addition to their heart failure. However, only 79% of the participants identified that they had heart disease. This finding was confusing to the investigator considering the study was being conducted in a cardiac clinic. However, when asked, the participants did not feel they had any serious heart issues. Sixty-six of the participants stated they had high blood pressure and 27% had diabetes. The leading comorbidity with CHF was hypertension with 66.4%. Women experienced hypertension (67.6%) slightly more often than men (65.8%). These findings were similar to those of studies conducted by Chin and Goldman (1998) and Levy, Larson, and Vasan (1996). However, future studies might consider combining heart disease and hypertension into one category representing cardiovascular disease.

Depression. Antidepressant medication was being taken by 16% of study participants; however, 14.2 % stated they had depression as a comorbidity. While men had a higher incidence of depression, women noted taking more medication for depression than men. In a qualitative study involving 23 CHF patients conducted by Bennett, Cordes, Westmoreland, Castro, and Donnelly (2000), women more often reported emotional symptoms of fear, depression, and sadness. In another study which conducted routine screening for depression and QOL in outpatients with CHF, almost

every third patient screened positive for depression. There was also a high prevalence rate of reduced QOL (Holzapfel, Muller-Tasch, Wild, Nelles, Hugo, & Junger, 2007).

Gottlieb et al. (2004) conducted a study on the influence of age, gender, and race on the prevalence of depression in CHF patients. They found that 48% of the patients scored as depressed, and women were more likely (64% were depressed and 36% were not) to be depressed than men (44% were depressed and 66% were not).

Costs and finances. Cost of medications (22%) and cost of medical care (30%) were noted as contributing to financial stress affecting quality of life. Women believed the cost of medications impaired their QOL (27%) as compared to men (19.7%). Men believed the cost of medical care impaired their QOL (30.3%) as compared to women (27%). However, women of “other” descent believed their cost of medications and medical care impaired their QOL an overwhelmingly 66.7%. In this study, this population was primarily Hispanic culture. These findings could be a reflection of Hispanic women having jobs that did not provide adequate salaries and/or health insurance. Therefore, these financial constraints could have an impact on their QOL.

Men had a higher household income and higher house value than did women. These findings are similar to a study conducted by Kim et al. (2000) who studied differences between men and women in anxiety early after acute myocardial infarction and found that women had a lower income than did men. In another study conducted by King (2002), women were predominantly in the lowest socio-economic group following a myocardial infarction. Chin and Goldman (1998) found that women were “poorer” than male respondents (p. 1036).

Perceived symptom management and QOL. The majority of participants (61.1%) rated their perceived general health status to be good or better. Their CHF symptom management rating was 7.2 on a scale of 0 to 10. Women perceived their general health status higher (70.2% as good or better) than men (56.2%). Women rated their perceived symptom management to be less (6.92) as compared to men (7.32). Men were hospitalized more ($n = 29$) than women were ($n = 9$) within a year time frame. These findings were consistent with those findings of Bennett, Baker, and Huster (1998) where women with CHF had high physical symptom impact and poor perceived physical health status. Also, in a study by Shahar, Lee, Kim, Duval, Barber, and Luepker (2004) men had a higher rate of hospitalizations than among women. In another study, Chin and Goldman (1998) found women with CHF had significantly lower scores for physical function and vitality than did men. Women had a higher perceived general health status mean than did men; however, men had a higher perceived CHF symptom management score mean than did women. The implications of this finding are not entirely clear. It may indicate that women may not require the same level of CHF symptom management as men or it could mean that women rate their QOL higher even when not managing their symptoms as well. This leads to the following question: "Do expectations of symptom management vary by gender?" Another question deserving further exploration might be "Do health conditions other than heart failure contribute to person's responses?"

Ejection fraction. Thirty eight percent ($n = 43$) of participants had an ejection fraction (EF) of $< 40\%$ and 62% ($n = 70$) had an EF of $\geq 40\%$. The overall mean EF% was 45.82, with African American women having the highest mean ($M = 54.25\%$) and

African American men having the lowest mean ($M = 38\%$) percentage. Women's mean EF% was 48.16; the mean EF% for men was 44.68. These findings are consistent with the findings of Friedman (2003) where the mean EF for men was 32.3 ($SD = 12.5$) as compared to the mean EF for women was 35 ($SD = 15$).

Hospitalizations. Overall, 61.1% of participants documented that they had not been hospitalized in over 1 year. Women were the highest (8.1%) in recent hospitalizations (those less than 3 months ago) as compared to men (5.3%). Similar results were found in a study by Ho, Pinsky, Kannel, and Levy (1993) where women were more often admitted to the hospital for CHF than men. In a study by Shahar, Lee, Kim, Duval, Barber, and Luepker (2004), the hospitalization rate, in contrast to this study, was about 50% higher among men than among women. Within one year of being hospitalized, 37% of male patients and 30% of female patients had died. By the end of a follow-up 5 to 6 years after the hospitalization, cumulative mortality reached 72% in men and 66% in women. In this same group, the hospitalization rate increased dramatically in ascending age groups: from a few dozen hospitalized patients per 100,000 patients ages 35 to 44 years to more 2000 per 100,000 patients ages 75 to 84. Shahar's study documented a high mortality of heart failure patients relative to the general population. A heart failure-related hospitalization conferred at least 10,000 excess deaths per 100,000 patients; more than 30,000 excess deaths per 100,000 elderly residents; and on average, 10 times mortality risk.

Shortness of breath was the primary symptom that prompted participants to go to the hospital. However, when looking at gender differences, women had shortness of

breath, swelling, and chest pain in that order. Men had shortness of breath, chest pain and then fatigue. In a study by Rector, Anand, and Cohn (2006), women reported more dyspnea and fatigue.

CHF classifications. The NYHA was recorded by both participants and their health care providers. Lower scores indicated less interference with function. The overall mean score of participants was 1.96; however, the health care providers' overall mean score was 2.43. Participants did not view their function with heart failure as severely affected as did their health care provider. Health care provider's responses on the NYHA classification were as follows: classification of I was 2.7%, classification of II was 55.8%, classification of III was 37.2%, and a classification of IV was 4.4%. These findings were similar to those of a study conducted by Krethong, Jirapaet, Jitpany, and Sloan (2008) in which most of the participants were placed in NYHA functional class II or III.

Perceived physical and mental health status. The physical health status (PCS) mean score for all participants was 37.83, with women's mean score (34.50) slightly less than men's mean scores (39.45). African American women had the lowest PCS mean scores of 31.2. These findings were similar to those found by Chin and Golman (1998) where women's PCS scores were lower than men's scores at study baseline.

The overall mental health status (MCS) mean score for all participants was 50.46. Mental health was perceived to be about the same by both genders, with women's mean score at 50.89 and men's 50.26. African American men had the lowest MCS mean score 47.05.

Health-related quality of life. The overall mean score for HRQOL, as measured by the MLHFQ, was 38.73 out of a possible score of 105. (Note: The HRQOL scores were reversed for this study so that a higher score meant higher HRQOL.) While the scores were not significantly different by gender, men had a mean score of 39.13 and women had a slightly lower mean score of 37.91. Men of “other” descent had the lowest mean score of 35.38. Compared with the health-related quality of life of other groups, De Jong, Moser, and Chung (2005) studied predictors of health status for heart failure patients and found a mean score of 51.62 ($SD = 22.58$), which they reported as poor HRQL. In a more recent study, Krethong, Jirapaet, Jitpanya, and Sloan (2008) found the mean score of HRQOL for participants was 55.13 ($SD = 20.63$). They reported these findings to indicate that participants perceived their HRQOL as moderate. According to the interpretation of these studies, the HRQOL mean score for the current study could be considered “moderate”.

Research Questions

Research question 1. Findings were presented for the first Research Question, “Are there differences in self-reported health status and HRQOL of men and women with a diagnosis of CHF? These findings indicated that there were no significant differences among gender categories on the dependent variable (HRQOL). Health status was found to be significant only for the physical component based on analysis of variance performed on each dependent variable as a follow-up procedure to the MANOVA. This finding of gender significance in relation to physical health is consistent with that of Chin and Goldman (1998).

Findings from this study can be compared to the study completed by Chin and Goldman (1998) because the instrument is the same. The difference between Chin and Goldman's study and this research study is that their study was longitudinal for one year survival and HRQOL following hospital admission of patients admitted with CHF. Their study looked at 179 patients at baseline (upon admission), women had lower scores than men for vitality, physical function, and PCS. These findings would be consistent with decompensated CHF. However, women still had lower scores than men at the 2-month time point for health perception, vitality, physical function, social function, and PCS. At 1 year, women continued to have lower scores than men for all domains except role mental function and MCS, which was consistent with the findings in this study.

Research question 2. Research Question 2, "Are there differences in age, race/ethnicity, living status, number of comorbidities, perceived general health status, and perceived symptom management of men and women with a diagnosis of CHF?" was addressed. Results for Research Question 2 demonstrated no statistical significant difference in gender and age, race/ethnicity, living status, number of comorbidities, perceived general health status, and perceived symptom management of men and women with a diagnosis of CHF. However, females had a higher mean age than males. The time of CHF diagnosis is not known, but as indicated within the literature (Chin & Goldman, 1998; Hussey & Hardin, 2003; and Rhodes & Bowles, 2002) diagnosis generally occurs later for women than men.

Analysis results for this question led to a revision of the original analysis planned for this study. Gender differences were not significant for perceived health status and

HRQOL, as had originally been conjectured by the researcher. Gender, therefore, was removed as an independent variable in the model to be tested. The results of these findings may be specific to this population.

Research question 3. The third research question was revised for analysis, with the independent variables of gender, race/ethnicity, and living status removed: “Are age, number of comorbidities, perceived general health status, perceived physical health status, perceived mental health, and perceived symptom management significant predictors of HRQOL?” This research question was addressed with hierarchical multiple regression analyses which allowed staged path analysis to examine the predicted relationships between the independent variables (IVs) and the dependent variable (DV) based on the theorized path model. The model was based on Wilson and Cleary’s (1995) health-related quality of life conceptual model.(Figure 1, p. 6). This model incorporates five main concepts (biological and physiological variables, symptom status, functional status, general health perceptions, and overall quality of life) which are staged in order. Path analysis is seen as a type of “causal modeling,” where the IVs may have a direct or indirect effect on the DV. The total effect is a result of the sum of the direct and indirect paths. By analyzing the data of all the paths, this analysis allows researchers to gain knowledge about the consistency between the data and theorized path model (Munro, 2001).

Path analysis was performed to determine the causal effects among the variables of the “Conceptual Model of Predictors to Health-Related Quality of Life” (see Figure 2, p. 108). The model includes five stages: (a) age and total number of comorbidities at

Stage 1 (Demographics); (b) Perceived Symptom Management at Stage 2 (Symptom Management); (c) Physical Component Score and Mental Component Score at Stage 3 (Functional Status); (d) Perceived General Health Status at Stage 4 (General Health Status); and (e) MMLHGQTO score at Stage 5 (Health Related Quality of Life). The dependent variable(s) at each stage was regressed on the independent variable(s) with a variance (R^2) given for each of the dependent variables. The variance discussed at each stage and associated path coefficients with each dependent variable (see Table 22) will be discussed.

Stage 2 (Symptom Management) of model testing involved the dependent variable of PSM and the two independent variables predicted to influence PMS: (a) age and (b) total number of comorbidities. They explained 15% of the variance in the outcome variable. The strongest predictor of Symptom Management was total number of comorbidities which had a negative influence ($\beta = -.331, p = .000$). In a study conducted by Gott et al. (2006), the number of comorbidities showed a significant association with PCS and MCS. For example, people reporting more than 1 comorbidity had a lower PCS score and a lower MCS score than those with none or 1. The current study, with the added variable of PSM preceding health status (PCS and MCS) similarly found that a greater number of comorbidities resulted in a decrease in PSM, meaning the higher the number of comorbidities, the poorer the perception of symptom management. The Stage 1 variables also had a direct path to the model's dependent variable, HRQOL. Path analysis revealed that age had a direct path to HRQOL, which was found to be negative ($\beta = -.205$) and significant ($p = .029$) which would mean the higher the participants age,

the lower the HRQOL. Comorbidities also had a direct path to HRQOL ($\beta = .149, p = .116$). This relationship was not significant and, though the computed Beta was low, it was a positive relationship. The direction of this relationship was not as anticipated, since it might be expected that one with more comorbidities would have a lower QOL.

Age was a modest Predictor of PSM. This relationship was predicted to be positive, that is, the older the individual, the better the PSM. Path analysis revealed that age had a positive ($\beta = .222$) and significant ($p = .000$) influence on PSM. Age also had a direct path to HRQOL, and this was found to be significant ($\beta = -.205, p = .05$). The ages of participants in this study ranged from 40 to 95 years with a mean age of 68 ($SD = 11.9$). Findings related to age and QOL have been mixed. Age has also been associated with a decrease in QOL (Gott et al., 2006), as was found in this study. Riedinger, Dracup, and Brecht (2000), though, found age to have a positive relationship with OOL. In evaluating the results of studies, it is important to consider the measures used. The measurement of HRQOL may be broad or narrow. The MHLFQ might be classified as a broad measure, including items that address physical function, mental health, symptoms, and social function (Albert, 1997).

At Stage 3 (Functional Status), the dependent variables of Physical Component Scale (PCS) and Mental Component Scale (MCS) represented the functional status response of the individual within the context of CHF. The independent variable predicted to influence the PCS and MCS was Perceived Symptom Management (PSM). It accounted for 15% and 23% of the variance in PCS and MCS, respectively. PSM was a moderate ($\beta = .392$) and significant predictor ($p = .000$) of PCS and a moderate ($\beta = .488$)

and significant predictor ($p = .000$) of MCS. These findings would support the importance of better symptom management in increasing perceived functional status.

The fourth dependent variable in Stage 4 (General Health Status) represents Perceived General Health Status. The two function status variables (PCS and MCS) were proposed to directly influence General Health Status. These accounted for 29% of the variance in the outcome variable of the two variables. The PCS was found to be a significant predictor of PGHS ($\beta = -.400, p = .000$). The MCS was found to be a significant predictor of PGHS ($\beta = -.320, p = .000$). These findings reflected how the patients perceived their overall health status through physical and mental well being. Although these predictions were not in the direction expected, this outcome may be explained by the person's general health outlook and rating of that general statement as compared to specific questions about one's health status (both physical and mental).

Model testing at Stage 5 (Health Related Quality of Life) examined the direct influence of Perceived General Health Status (PGHS), as well as the direct effects of the two Stage 1 variables (comorbidities and age) discussed earlier. Perceived health status was a 1-item general rating of how the person perceived health status, thus it was a narrow measure with limited variance. PGHS was a significant predictor ($\beta = .192, p = .05$) of HRQOL, though it explained only about 3% of the variance in HRQOL. As noted earlier, the MLHFQ is a broad measure of QOL, whereas the PGHS captures only the person's self-rating of health. Globally, individuals may tend to rate their health status higher than when they rate more specific aspects of their health as requested by the array of questions on the MLHFQ.

In summary, the strongest predictor in the HRQOL model was the influence of PSM on MCS. This finding suggests that participants' perception of their symptom management influences their mental health well being. This may indicate the importance of one's mental health in coping with the chronic condition of CHF. This finding deserves further exploration. Total number of comorbidities was found not to be a significant predictor of HRQOL.

Research question 4. Research Question 4, revised, was, "Do symptom status (i.e., perceived symptom management), functional status (i.e., perceived physical health status and perceived mental health status), and general health perceptions (i.e., perceived general health status) serve as mediating variables between the exogenous variables (i.e., age and comorbidities) and HRQOL?" The variables PSM, PCS, MCS and PGHS serve as mediating variables (see Figure 2, p. 108). Findings suggested that age, but not the number of comorbidities, be retained in the HRQOL model as an exogenous variable. The number of comorbidities did not have a significant direct influence on HRQOL, and its influence was not increased by other variables in the model.

Research question 5. The fifth Research Question was "Is there agreement of the New York Heart Association's (NYHA) Functional Class ratings made by the participant and his/her health care provider?" Findings indicated that patient's perceptions and provider's assessments of their functional status were poor, though they were beyond the level of chance. There was only "slight" agreement between the patient and provider regarding the NYHA functional class ratings (Viera & Garrett, 2005). This finding was consistent with that of Subramanian, Weiner, Gradus-Pizlo, Wu, Tu, and Murray (2005)

that patient perception (n = 156) and provider assessment showed slight agreement either over the phone or in person. In that study, however, the patient's NYHA class was derived, using an algorithm, from the patient's response to the Kansas City Cardiomyopathy Questionnaire (KCCQ). In the current research, the actual NYHA classifications were obtained from the patients and health care providers in person in the clinic setting.

Participant's perception of their NYHA's classification was lower than the provider's classification. This indicated that participants classified themselves as having none to slight limitation in physical activity, whereas their providers classified them as having slight to marked limitations. The study by Subramanian, Weiner, Gradus-Pizlo, Wu, Tu, and Murray (2005) found the alternative, that patients placed themselves in a worse category than did their health care providers. However, the NYHA classification does not take age into consideration, which may need to be investigated further. Also, as mentioned previously, 38% (n = 43) of participants had an ejection fraction (EF) of < 40% and 62% (n = 70) had an EF of \geq 40%. This could have been a contributing factor because less than 40% indicates systolic heart failure and greater than 40% indicates diastolic failure.

Study Methodology

Data collection was conducted at two different cardiology clinics to enhance generalizability by including participants of different ages and race/ethnicities. The participants represented middle to older adults who were diagnosed with CHF.

Cardiology clinics were used as sites for recruiting participants since individuals were there because they were receiving treatment for their heart failure.

The physicians and nurse practitioner in the two clinics were extremely helpful with suggesting dates for the study based on activities within the office and related screening for participants who might be interested in participating in the study. Flyers were placed in the clinics prior to the start of the study; these were found to be helpful to recruitment.

A major weakness of this study was that participants primarily had a pay source that assisted with paying for their healthcare. This excluded many adults who did not have a primary pay source. The majority of adults in this study were older adults ($M = 68.41$, $SD = 11.86$), living independently, and able to drive to the clinics. There were a few participants whose family members helped with transportation. This study included participants in urban as well as rural settings. Since the study focused on adults who were living independently and managing their heart failure, results cannot be generalized to adults who are living in either assisted living centers or nursing homes.

Conclusions and Implications

The findings from this study support the conclusions from previous research that HRQOL among those with congestive heart failure (CHF) is impacted by numerous variables. The caution is that each conclusion has to be considered within the context of how HRQOL was defined and measured for that particular study. Information from this exploratory study increases the support for the idea that changes made in symptom management can bring about positive changes in physical and emotional wellbeing,

perceived general health status, and, ultimately, HRQOL. The finding that the success of symptom management was related to mental health function suggests that teaching CHF patients how to use psychological coping strategies to deal with their symptoms may be important.

The results of model testing provide health care providers with information that can be used in guiding treatment approaches to help improve QOL. Wilson and Cleary's (1995) framework was supported by the findings that age, symptom management, functional status, and general health status influence HRQOL in patients diagnosed with CHF. Future model testing might be done with the subtraction of comorbidities and the addition of other variables yet to be identified.

The implications for the nursing profession are the need to disseminate the findings from this study to nurses, patient's and their family members, and the general public. Among the findings that have clear clinical implications are the following:

1. More discussion of function between patients and health care providers needs to occur.
2. Symptom management is important to QOL outcomes, thus emphasis on ensuring that individual patients learn to use management strategies appropriately is important.
3. Socio-economic status may play a role in one's QOL, for example, whether or not individuals have the finances to purchase medications or follow-up their care for CHF. In some cases, individuals with CHF may not be able to work, which could cause further difficulties in QOL.

This information needs to move beyond the clinical setting, allowing it to be disseminated through presentations and publications. Providing this information to health care providers will allow them to gain a realistic picture of the patient's perception of QOL, realizing that the patient's perception may not always be the same as the health care providers.

Recommendations for Further Study

Based on the findings of this study, recommendations for future study are

1. There is a need to gain an understanding of the meaning of the difference in health status and HRQOL between men and women. A qualitative exploration of these phenomena could provide better understanding.
2. Conduct longitudinal studies of health status and HRQOL in heart failure, preferably using the same instruments as previous research.
3. Develop and test interventions designed to improve health status and HRQOL in heart failure patients.
4. Determine whether the cost of medication and medical care impairs the QOL for women of non-white ethnicity.
5. Determine whether expectations of symptom management vary by gender.
6. Conduct studies in populations with more variation and different types of insurance, or financial health care coverage, and socioeconomic status.
7. Explore the removal of PGHS as a variable in the model.

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APPENDIX A

Recruitment Flyer

Patients Diagnosed with Congestive Heart Failure Needed for a Research Study

The purpose of this study is to learn more about the Health Status and Health-Related Quality of Life of persons with congestive heart failure (CHF).

Participation in this study is voluntary.

For more information, please contact the front desk or Karen Landry (at the number below).

Karen Ainsworth Landry, RN, MSN
Doctoral Candidate
Texas Woman's University
318/677-3100 or 3109

APPENDIX B

Receptionist Script

Receptionist script

Receptionist:

Would you be interested in participating in a research study that is looking at health status and health-related quality of life of persons diagnosed with congestive heart failure (or CHF)? Participation in this study is voluntary. This study is being conducted by a nurse, Karen Ainsworth Landry, for her doctoral dissertation at Texas Woman's University. She is interested in learning more about these characteristics in order to better plan nursing care.

Patient:

If "Yes".

Receptionist:

Thank you, the primary investigator or the nurse liaison will be with you in a few minutes.

Patient:

If "No".

Receptionist:

Thank you..

Note: Patient may ask something like:

"How long will this take?"

Answer: At most, about 35 minutes.

"What do I have to do?"

Answer: Participation involves filling out 3 questionnaires.

APPENDIX C

Consent Form

TEXAS WOMAN'S UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH

Title: Health Status and Health-Related Quality of Life in Congestive Heart Failure

Investigator: Karen Ainsworth Landry..... 318/795-9488
Advisor: Gail Davis, EdD..... 940/898-2401

Explanation and Purpose of the Research

You are being asked to participate in a research study for Ms. Karen Ainsworth Landry's dissertation's study at Texas Woman's University. The purpose of this research is to determine the relationship between certain characteristics of your health status and health-related quality of life with congestive heart failure.

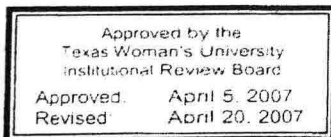
Research Procedures

Participants in this study, patients with congestive heart failure, will complete a general information form (Part A) and two questionnaires. You will be given these by the researcher or a nurse in the clinic, and the time for completing them should not exceed 35 minutes. The researcher or nurse will be available to answer questions you may have while filling them out. This will take place in a private area within the clinic. Your health care provider will complete Part B of your general information form. He or she will document how your heart is functioning (functional classification) and how it is pumping (ejection fraction).

Potential Risks

Potential risks related to your participation in the study include fatigue and emotional discomfort while completing the questionnaires. To avoid fatigue, you may take a break (or breaks) while completing the questionnaires as needed. If you experience fatigue or emotional discomfort while completing the questionnaires, you may stop or postpone participation at any time please let the P.I. or nurse liaison know. If completion of the forms are too tiring, the P.I. or nurse liaison will volunteer to make the marks on the form as directed by you. If you feel as though you need to discuss this emotional discomfort with a professional, the investigator or nurse liaison will provide you with a referral list of counselors' names and phone numbers.

Another possible risk to you as a result of your participation in this study is release of confidential information. Confidentiality will be protected to the extent that is allowed by law. The interview will take place in a private area within the clinic. A code number, such as 001 and 002, will be used on the questionnaires and the general information form (Parts A and B) instead of your name to organize the information. Only the investigator



Participant initials
Page 1 of 2

and her advisor will have access to the questionnaires and general information form. These completed forms will be stored in a locked filing cabinet in the investigator's office. They will be shredded within 5 years. It is anticipated that the results of this study will be published in the investigator's dissertation as well as in other research publications. However, no names or other identifying information will be included in any publication.

Another potential risk to you is coercion. Your participation in this research study is voluntary and you may withdraw at any time. Your health care will not be affected in anyway based on your decision regarding participation. Your health care provider will not be informed of your decision regarding participation.

The researcher will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

Participation and Benefits

Your involvement in this research study is completely voluntary, and you may discontinue your participation in the study at any time without penalty. The only direct benefit of this study to you is that at the completion of the study a summary of the results will be mailed to you upon request.*

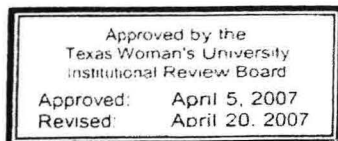
Questions Regarding the Study

If you have any questions about the research study you may ask the researchers; their phone numbers are at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the Texas Woman's University Office of Research and Sponsored Programs at 940-898-3378 or via e-mail at IRB@twu.edu. You will be given a copy of this signed and dated consent form to keep.

Signature of Participant

Date

* If you would like receive a summary of the results of this study, please provide an address to which this summary should be sent:



APPENDIX D

Agencies Permission to Conduct Study



March 2, 2007

Karen Landry
7343 University Drive
Shreveport, LA 71105

Dear Ms. Landry:

I am pleased to know that you're planning a study that is aimed at health status and health related quality of life patients with congestive heart failure. This is a topic that is of interest to us in improving the quality of care in our institution. We would be pleased for you to access our patients to determine if they would like to participate in your study. A person who will serve as a liaison from our staff to work out the procedures with you will be assigned to you at a later date. Prior to beginning your recruitment of participants, please provide us with a copy of the human subjects approval letter.

We look forward to working with you.

Dissertation/Theses signature page is here.

To protect individuals we have covered their signatures.

PREMIER HEART SPECIALISTS, PA
Practice of Cardiac & Peripheral Interventional Cardiology
Dr. Ajit V. Adyanthaya, MD, FACC
Diplomate American Board of Cardiovascular Diseases
Dr. P.V. Balakrishnan, MD, DM, FACC, FSCAI
Diplomate American Board of Cardiovascular Diseases

June 24, 2006

Premier Heart Specialists, P.A.
Dr. P. V. Balakrishnan, MD, DM
Dr. A. V. Adyanthaya, MD
11914 Astoria Blvd. Suite 410
Houston, TX 77089

Dear Ms. Landry:

I'm pleased to know that you're planning a study that is aimed at examining specific variables as predictors of health status and of quality of life in women with congestive heart failure. This is a topic that is of interest to us in improving the quality of care in our institution. We would be pleased for you to access our patients to determine if they would like to participate in your study. The person who will serve as a liaison from our staff to work out the procedures with you is Brandi Pipes, RN, BSN, student adult APN. Prior to beginning your recruitment of participants, please provide us with a copy of the human subjects approval letter.

We look forward to working with you.

Sincerely,

Dissertation/Theses signature page is here.

To protect individuals we have covered their signatures.

APPENDIX E

Institutional Review Committee Letter

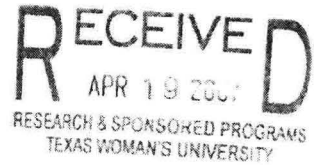
Karen Ainsworth Landry
7343 University Dr. Shreveport, LA 71105
(318) 795-9488

18 April 2007

Dr. David Nichols, Chair
Institutional Review Board
Box 425619
Denton, TX 76204-5619

APPROVED
4/20/2007

[Signature]



Dear Dr. Nichols,

Based on suggestions from committee members during my Prospectus Defense, I am sending a revised IRB application, General Information Form (GIF) and consent form. I have highlighted areas that were added. Basically, these changes are requested in order to determine whether the patient's functional classification rating matches that of the health care provider. The procedure used will maintain anonymity; the health care provider will not know which patients are or are not participating.

On the GIF form, an addition section was added. There will be one section for participants to complete (Part A) and another section (Part B) that the health care provider will complete. Part B will be placed on a cabinet within each patient's examination room. Each form will be pre-numbered in order to provide anonymity for all patients (those who do participate and those who do not). Only the forms for those participating in the study will be collected; those for non-participants will be shredded and discarded when retrieved by the data collector.

Revisions (which are highlighted) were made to the IRB application. These revisions include:

- #1 - Research Questions # 4 & # 5 (Q #4 was already implied from Q #3, and Q #5 was suggested by the physician in the Dallas agency who is serving on my dissertation committee. I will send a letter to the Houston agency for approval to collect this added data by the health care provider)
- #4 - Included the procedure for Part B of the GIF
- #9 - GIF (Part B)
- #10 - GIF (Parts A and B); information was added to loss of confidentiality and coercion sections
- #11 b & c - GIF (Part B)

Also, I am sending the consent form with revisions (which are highlighted).

Please contact me if you have any questions at the address or phone number above, or at landryk@nsula.edu

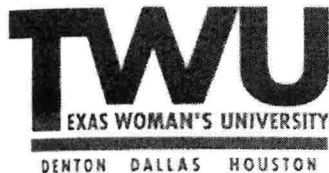
Sincerely,

Karen Ainsworth Landry

Karen Ainsworth Landry

APPENDIX F

Graduate School Approval Letter



The Graduate School
P.O. Box 425649, Denton, TX 76204-5649
940-898-3415 Fax 940-898-3412

0671143

April 23, 2007

Ms. Karen Ainsworth Landry
7343 University Drive
Shreveport LA 71105

Dear Ms. Landry:

I have received and approved the prospectus entitled "**Health Status and Helath-Related Quality of Live in Congestive Heart Failure**" for your Dissertation research project.

Best wishes to you in the research and writing of your project.

Dissertation/Theses signature page is here.

To protect individuals we have covered their signatures.

APPENDIX G

General Information Form

General Information Form

Health Status and Health-Related Quality of Life in Congestive Heart Failure

Patient's Response – Part A

**Please circle which category you currently find yourself
belonging to.**

GENDER

1. Female
2. Male

AGE _____

ETHNICITY/RACE

1. American Indian or Alaska Native
2. Asian
3. Black or African-American
4. Hispanic or Latino
5. Not Hispanic or Latino
6. Native Hawaiian or Other Pacific Islander
7. White

LIVING STATUS

1. Lives alone
2. Lives with someone
3. Lives in a residential setting

What is your Zip code? _____

PERCEIVED GENERAL HEALTH STATUS

Would you say your health in general is?

1. Excellent
2. Very good
3. Good
4. Fair
5. Poor

PERCEIVED SYMPTOM MANAGEMENT

Please circle the number which best describes your symptom management with congestive heart failure.

1	2	3	4	5	6	7	8	9	10
Not Well									Extremely
at All									Well

COMORBIDITIES (Please circle all that apply)

1. Heart Disease
2. High blood pressure
3. Lung disease
4. Diabetes
5. Ulcer or stomach disease
6. Kidney disease
7. Liver disease
8. Anemia or other blood disease
9. Cancer
10. Depression
11. Osteoarthritis, degenerative arthritis
12. Back pain
13. Rheumatoid arthritis
14. Thyroid disease
15. Obesity
16. Autoimmune disease
17. Sleep Apnea
18. Other

What is your ejection fraction (your hearts ability to pump blood)?

1. Greater than 40%
2. Equal to 40% or less than 40%
3. Unknown

Are you currently taking an anti-depressant medication(s)?

1. Yes
2. No

Are the costs of your medications causing restraints on your quality-of-life?

1. Yes
2. No

Is the cost of your medical care causing financial stress on your quality-of-life?

1. Yes
2. No

PERCEIVED NEW YORK HEART ASSOCIATION'S (NYHA) FUNCTIONAL CLASS

Please circle the number which best describes your congestive heart failure class.

1. You have no limitation of activities; you suffer no symptoms from ordinary activities.
2. You have slight, mild limitation of activity; you are comfortable with rest or with mild exertion.
3. You have marked limitation of activity; you are comfortable only at rest.
4. You should be at complete rest, confined to bed or chair; any physical activity brings on discomfort and symptoms occur at rest.

When were you last admitted to the hospital?

1. Less than 3 months
2. 3 months to less than 6 months
3. 6 months to less than 1 year
4. 1 year or greater
5. Never

What symptoms prompted you to go to the hospital? (Check all that apply.)

1. Swelling
2. Shortness of Breath
3. Fatigue (Tiredness)
4. Defibrillator responded
5. Chest pain
6. Other _____

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE!

General Information Form

Health Status and Health-Related Quality of Life in Congestive Heart Failure

Health Care Provider's Response – Part B

Patient's EF% - _____

NYHA classification - 1 2 3 4

APPENDIX H






SF-36 Health Survey Version 2.0

Your Health and Well-Being






This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Yes, limited a lot	Yes, limited a little	No, not limited at all
▼	▼	▼

- a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports ☐ 1 ☐ 2 ☐ 3
- b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf ☐ 1 ☐ 2 ☐ 3
- c Lifting or carrying groceries ☐ 1 ☐ 2 ☐ 3
- d Climbing several flights of stairs ☐ 1 ☐ 2 ☐ 3
- e Climbing one flight of stairs ☐ 1 ☐ 2 ☐ 3
- f Bending, kneeling, or stooping ☐ 1 ☐ 2 ☐ 3
- g Walking more than a mile ☐ 1 ☐ 2 ☐ 3
- h Walking several hundred yards ☐ 1 ☐ 2 ☐ 3
- i Walking one hundred yards ☐ 1 ☐ 2 ☐ 3
- j Bathing or dressing yourself ☐ 1 ☐ 2 ☐ 3

4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

- ☐ 1 Cut down on the amount of time you spent on work or other activities ☐ 2 ☐ 3 ☐ 4 ☐ 5
- ☐ 1 Accomplished less than you would like ☐ 2 ☐ 3 ☐ 4 ☐ 5
- ☐ 1 Were limited in the kind of work or other activities ☐ 2 ☐ 3 ☐ 4 ☐ 5
- ☐ 1 Had difficulty performing the work or other activities (for example, it took extra effort) ☐ 2 ☐ 3 ☐ 4 ☐ 5

5. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

- ☐ 1 Cut down on the amount of time you spent on work or other activities ☐ 2 ☐ 3 ☐ 4 ☐ 5
- ☐ 1 Accomplished less than you would like ☐ 2 ☐ 3 ☐ 4 ☐ 5
- ☐ 1 Did work or other activities less carefully than usual ☐ 2 ☐ 3 ☐ 4 ☐ 5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. Have you been very nervous?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c. Have you felt so down in the dumps that nothing could cheer you up?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
d. Have you felt calm and peaceful?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
e. Did you have a lot of energy?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
f. Have you felt downhearted and depressed?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
g. Did you feel worn out?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
h. Have you been happy?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
i. Did you feel tired?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true ▼	Mostly true ▼	Don't know ▼	Mostly false ▼	Definitely false ▼
a I seem to get sick a little easier than other people.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b I am as healthy as anybody I know.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c I expect my health to get worse.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
d My health is excellent.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

THANK YOU FOR COMPLETING THESE QUESTIONS!

APPENDIX I

Minnesota Living With Heart Failure Questionnaire

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent

you from living as you wanted during
the past month (4 weeks) by -

	No	Very Little				Very Much
1. causing swelling in your ankles or legs?	0	1	2	3	4	5
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making your working around the house or yard difficult?	0	1	2	3	4	5
5. making your going places away from home difficult?	0	1	2	3	4	5
6. making your sleeping well at night difficult?	0	1	2	3	4	5
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	1	2	3	4	5
20. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21. making you feel depressed?	0	1	2	3	4	5

APPENDIX J

Permission to Use SF-36 Health Survey Version 2.0

LICENSE AGREEMENT

License Number: F1-030906-25727

This License Agreement is entered into, by, and between QualityMetric Incorporated (the "Licensor"), 640 George Washington Highway, Lincoln, RI 02865 and Texas Woman's University (the "Licensee"), Karen Landry, 7343 University Drive, Shreveport, LA, 71105.

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- SF-36v2™ Health Surveys

United States (English) – Standard Recall

This license cannot be assigned or transferred, nor can it be used by the Licensee to obtain data to be used in studies other than "I am a PhD student in the College of Nursing at Texas Woman's University at Denton, TX. I would like to use the SF-36 to collect data for my dissertation. Thank you, Karen Ainsworth Landry".

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Confidentiality

The Licensee acknowledges that the Intellectual Property is a valued asset of the Licensor, that the Intellectual Property is of great commercial value to the Licensor, and that the value of the Intellectual Property would be significantly impaired by the unauthorized distribution or use of the Intellectual Property. The Licensee shall protect the Intellectual Property from unauthorized use by its employees, agents and customers and shall limit the use to the permission granted to Licensee by this Agreement.

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The Licensee understands and acknowledges that a complex and sophisticated product such as the Intellectual Property is inherently subject to undiscovered defects. The Licensor cannot and does not represent or warrant to the Licensee that the Intellectual Property is free from such defects, that operation of the Intellectual Property will be uninterrupted or error-free, or that its results will be effective or suitable with respect to any particular application. Furthermore, the Licensor does not represent or warrant that the Intellectual Property is capable of industrial realization or commercial exploitation, the risks of which are being assumed solely by the Licensee. THE INTELLECTUAL PROPERTY IS LICENSED AS-IS, AND THE LICENSOR DISCLAIMS ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY REPRESENTATIONS OR WARRANTIES AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, RESPECTING ANY OF THE INTELLECTUAL PROPERTY OR ANY OTHER MATTER RELATED TO THIS AGREEMENT.

Term and Termination

This License Agreement shall be effective from April 3, 2006, the date the Licensee will start reproducing the Licensed Survey. This License Agreement shall terminate on April 3, 2007, the date the Licensee will score the last Licensed Survey.

Licensor may terminate this Agreement in the event of a material breach of its terms by Licensee or any of its agents by written notice delivered at least fifteen (15) days prior to the effective date of the termination.

License Fee

This License ("the License") is royalty free. This License is limited to the number of survey administrations in the languages indicated on the first page of this License.

Administration Fee

The administration fee for the licensed surveys ("the License") is \$100.00.

This License is limited to the languages indicated on the first page of this License.

Payment Terms

Licensee shall pay \$100.00 upon execution of this License Agreement, per the enclosed invoice.

LICENSE AGREEMENT

License Number: F1-030906-25727

Scoring Manuals

Licensee is required to have purchased or purchase the manuals indicated below for the Licensed Survey(s) indicated on the first page of this License.

- How to Score Version 2 of SF-36® Health Survey

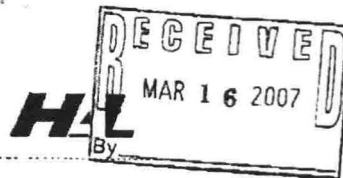
Other Services

In addition to the rights described above, Licensee may access Licensor's Online Scoring Service for an additional fee.

EXECUTED, as of the date set forth in the paragraph captioned Terms and Termination, by the duly authorized representatives as set forth below. By Executing this License Agreement, the undersigned Licensee represents that it is an organization that will only use the Licensed Survey(s) in the languages indicated on the first page and according to the terms of this License to obtain data for un-funded scholarly research.

Texas Woman's University
Karen Landry
7343 University Drive
Shreveport, LA 71105

Signature: Karen A. Landry
Name: Karen Ausworth Landry
Title: Phd Student
Date: 3/31/06



LICENSE AGREEMENT AMENDMENT

License Number: F1-030906-25727

Subject to the full execution of this letter amendment, Karen Landry ("Licensee") hereby amends License Agreement # F1-030906-25727 with Licensors as follows:

The Parties shall amend the Contract Start and End Dates of Study "I am a PhD student in the College of Nursing at Texas Woman's University at Denton, TX. I would like to use the SF-36 to collect data for my dissertation. Thank you, Karen Ainsworth Landry" under License #F1-030906-25727 as follows:

- The Contract Start Date shall be April 15, 2007.
- The Contract End Date shall be April 15, 2008.

All other terms and conditions of the Agreement shall continue in full force and effect during the extended term of this Agreement.

If foregoing terms and conditions are acceptable, please have an authorized representative of Licensee sign and date below.

Licensee

Karen Landry

7343 University Drive

Shreveport, LA 71105

Licensors

QualityMetric Incorporated

640 George Washington Highway

Lincoln, RI 02865

Signature:

Name:

Title:

Date:

Karen A. Landry
KAREN A. LANDRY
Principal Investigator
PhD Student
3/12/07

Signature:

Name:

Title:

Date:

Dawn Giles

V.P. Marketing & Sales

March 12, 2007

Customer Initials: KAL

Date Signed: 3/12/07

Page 1 of 1

Amendment Template - Contract Dates w/o Fee - Rev 05/23/2006

APPENDIX K

Permission to Use Minnesota Living With Heart Failure Questionnaire

**Minnesota LIVING WITH HEART FAILURE® Questionnaire
COPYRIGHT USER'S LICENSE**

The Regents of the University of Minnesota (hereafter referred to as "UNIVERSITY"), a constitutional corporation of the State of Minnesota having an office and principal place of business at 450 McNamara Alumni Center, 200 Oak St. SE, Minneapolis, MN 55455 has created a copyrighted WORK entitled the Minnesota LIVING WITH HEART FAILURE® Questionnaire intended for use by authorized health care professionals and researchers, and desires to make the WORK available for use worldwide.

Completion of this COPYRIGHT USER'S LICENSE ("LICENSE"), whereby the LICENSEE agrees to the terms specified herein, is required to use the WORK. Users must legibly complete items 1.3, 6.1, 6.2 and 7.2, if applicable. A signature and date on also required on the last page prior to submitting this document as directed in item 7.1.

ARTICLE I - DEFINITIONS

1.1 WORK means the Minnesota LIVING WITH HEART FAILURE® Questionnaire and Instructions for Data Collection and Scoring. This WORK is in the English language, and is identified as U/M Docket #94019. An electronic copy of the WORK and supplemental information including information about translations is available at www.mhbfq.org.

1.2 APPROVED COPIES means duplicates of the WORK that shall include the following statements:

©1986 Regents of the University of Minnesota, All rights reserved. Do not copy or reproduce without permission. LIVING WITH HEART FAILURE® is a registered trademark of the Regents of the University of Minnesota.

1.3 LICENSEE means (complete all of the following)

Name of person or organization: Karen Ainsworth Landry

Address: 7343 University Dr., Shreveport, LA 71105

Telephone number: 318-795-9488

Facsimile number: 318-677-3127

Electronic mail address: landryk@nsula.edu

ARTICLE II - LICENSE

2.1 UNIVERSITY grants to LICENSEE the right to reproduce the WORK and use APPROVED COPIES of the WORK for purposes described below in Article 6.1 upon, (i) submission of a completed LICENSE to the UNIVERSITY, (ii) payment to the UNIVERSITY of the applicable nonrefundable LICENSE FEE specified below in Article 6.2, and (iii) notification of acceptance of (i) and (ii) by the UNIVERSITY. The EFFECTIVE DATE of this LICENSE is the date of (iii).

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- 2.5 LICENSEE may not assign its license rights under this LICENSE to any entity other than a wholly-owned subsidiary of the LICENSEE.

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- 3.2 UNIVERSITY may terminate this LICENSE upon breach of the LICENSE by LICENSEE. UNIVERSITY shall give LICENSEE written notice of the breach and notice of the intent to terminate. If LICENSEE does not cure the breach within thirty (30) days of the notice, the LICENSE shall terminate. Upon such termination, LICENSEE's right to use the WORK shall terminate.
- 3.3 Termination of this LICENSE shall not extinguish any of LICENSEE's obligations under this LICENSE which, by their terms, continue after the date of such termination or expiration.

ARTICLE IV - PROTECTION OF PROPRIETARY RIGHTS

- 4.1 LICENSEE shall take all steps reasonable to protect UNIVERSITY's ownership rights in the WORK. LICENSEE shall not distribute copies of the WORK to third parties or employees without appropriate notice, agreement, and/or instruction with respect to use, copying, modification, and copyright protection of the WORK.
- 4.2 LICENSEE will not remove the UNIVERSITY copyright notice and/or other proprietary notices.

ARTICLE V - WARRANTIES AND LIMITATIONS; INDEMNIFICATION

- 5.1 UNIVERSITY and LICENSEE warrant that they have the right to enter into this LICENSE and the ability to comply with its terms.
- 5.2 UNIVERSITY MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED. BY WAY OF EXAMPLE, BUT NOT LIMITATION, UNIVERSITY MAKES NO REPRESENTATIONS OR WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OF THE WORK. UNIVERSITY SHALL NOT BE HELD LIABLE FOR ANY LIABILITY OR FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OF THE WORK.
- 5.3 LICENSEE agrees to indemnify and hold UNIVERSITY harmless against any claims or damages resulting from LICENSEE's use of the WORK including all liability to third parties arising from the negligence of LICENSEE. LICENSEE assumes no responsibility for any third party claims that the WORK, unmodified by LICENSEE, infringes a copyright of the third party, or for damages arising from the willful or negligent behavior or conduct of UNIVERSITY.

ARTICLE VI - LICENSED USE OF WORK AND FEE

6.1.1 The LICENSEE's use of the WORK under this LICENSE is restricted to uses indicated by an "X" in a box preceding each intended use. LICENSE FEES are in U.S. dollars.

☒ The LICENSEE is a student or teacher who will use the WORK only for a student project(s) or didactic purposes. LICENSE FEE is waived.

☐ The LICENSEE is a health care professional or health care organization who will use the WORK only in the care of patients or to evaluate in-house services. LICENSE FEE is \$500.

☐ The LICENSEE is a principal investigator who will use the WORK in not-for-profit research projects. LICENSE FEE is \$500 per project. Type the title(s) of each project to be covered by this LICENSE in the following space:

☐ The LICENSEE is a pharmaceutical, medical device, biotechnology, disease management or other for-profit entity who will use the WORK to evaluate a product or service that is in development or on the market. LICENSE FEE is \$2,500 per protocol. Type the title and number of each protocol to be covered by this LICENSE in the following space.

6.2 Enter the total of all applicable LICENSE FEES from Article 6.1. \$0.00

ARTICLE VII - SUBMISSION OF LICENSE & PAYMENT; NOTIFICATION OF ACCEPTANCE

7.1 The fully completed LICENSE including signature and LICENSE FEE listed above in Article 6.2 should be sent to the following address. An incomplete or illegible LICENSE will not be accepted. The UNIVERSITY will not send a separate invoice. Please keep a copy of your submission for your records. Payment should be sent as a check for U.S. dollars made payable to the University of Minnesota. If you do not send the completed LICENSE and payment together, make sure your payment identifies the LICENSEE and the Minnesota LIVING WITH HEART FAILURE® Questionnaire as the reason sending the payment to the UNIVERSITY.

Send completed LICENSE and LICENSE FEE to;

Minnesota LIVING WITH HEART FAILURE® Questionnaire
 Patents & Technology Marketing
 University of Minnesota
 450 McNamara Alumni Center
 200 Oak St. SE
 Minneapolis, MN 55455-2070

7.2 An electronic notification of acceptance will be sent by the UNIVERSITY when both a completed LICENSE and LICENSE FEE are received. If this notification is to be sent to an electronic address other than the one listed above in article 1.3, type the person's name and electronic address here:

Name: Email address:

ARTICLE VIII - MISCELLANEOUS

- 8.1 All questions about the LICENSE or WORK should be sent to info@mlhfg.org. The UNIVERSITY is under no obligation to provide support for the WORK.
- 8.2 This LICENSE contains the entire agreement of the parties concerning this subject matter and supersedes all other previous understandings and statements, written or oral, concerning this matter.
- 8.3 This LICENSE is binding upon and shall inure to the benefit of the LICENSEE's successors and/or assigns.
- 8.4 This LICENSE shall be interpreted and applied in accordance with the laws of the State of Minnesota.
- 8.5 Headings are for convenience only and are not to be used in interpreting this LICENSE.
- 8.6 The terms of this LICENSE cannot be orally modified. A modification is not effective unless it is in writing and signed by the LICENSEE and the UNIVERSITY.

IN WITNESS WHEREOF, the LICENSEE agrees to the above terms by the signature below of their duly authorized representatives.

(LICENSEE)

By: Karen Ainsworth Landry
(authorized signature)

Karen Ainsworth Landry
(print name and title)

Date: 3/9/06

LIVING WITH HEART FAILURE® is a registered trademark of the Regents of the University of Minnesota.

APPENDIX L

Permission to Use Wilson and Cleary's (1995) Health-Related Quality of Life Conceptual Model

Karen Landry

From: Rachel Stanaszek [Rachel.Stanaszek@ama-assn.org]
Sent: Wednesday, March 05, 2008 3:20 PM
To: Karen Landry
Subject: Permission Granted - Print.rtf

March 5, 2008

Karen Landry
 Texas Women's University

Journal Name	Year	Citation	Item(s) used
JAMA	1995	273:59-65	Figure

Intended Use: Material will be used in a doctoral dissertation.

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Best wishes,

Rhonda Bailey Brown
 Permission Assistant
 Publishing Operations
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3/5/2008